Sunshine Act Meetings

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This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

UNITED STATES INTERNATIONAL TRADE COMMISSION

[USITC SE-94-17]

TIME AND DATE: May 26, 1994 at 2:30 p.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436.

STATUS: Open to the public

1. Agenda for future meeting
2. Minutes
3. Ratification List
4. Inv. No. 731-TA-651 (Final) (Silicon Carbide from China)—briefing and vote
5. Outstanding action jacket:
   1. ID-94-010; Inv. No. 332-350 (Monitoring of U.S. Imports of Tomatoes).

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

CONTACT PERSON FOR MORE INFORMATION: Donna R. Koehnke, Secretary, (202) 205-2000.

Issued: May 18, 1994.

Donna R. Koehnke,

Secretary.

[FR Doc. 94-12641 Filed 5-19-94; 2:28 pm]

BILLING CODE 7020-02-P

NATIONAL WOMEN'S BUSINESS COUNCIL

ACTION: Notice of meeting.

SUMMARY: In accordance with the Women's Business Ownership Act, Public Law 100-533 as amended, the National Women's Business Council announces a forthcoming Council Meeting. The meeting will cover action items to be taken by the National Women's Business Council in Fiscal Year 1994 including but not limited to increasing procurement opportunities and access to capital for women business owners.

DATE: June 2, 1994, 4 p.m. to 5 p.m.

ADDRESS: Hilton Hotel and Towers, 720 S. Michigan Avenue, Chicago, Illinois.

STATUS: Open to the public.

CONTACT: For further information contact Amy Millman, Executive Director or Juliette Tracey, Deputy Director, National Women's Business Council, 409 Third Street, SW., suite 5850, Washington, DC 20024, (202) 205-3850.

Gilda Washington,

Administrative Officer, National Women's Business Council.

[FR Doc. 94-12619 Filed 5-19-94; 11:49 am]

BILLING CODE 6820-AB-M

TENNESSEE VALLEY AUTHORITY

Meeting No. 1466

TIME AND DATE: 10 a.m. (EDT), May 25, 1994.

PLACE: TVA Knoxville Office Complex, 400 West Summit Hill Drive, Knoxville, Tennessee.

STATUS: Open.

Agenda

Approval of minutes of meeting held on April 26, 1994.

Discussion item

1. Integrated Resource Planning.

Action Items

New Business

E—Real Property

E1. Release of a Restrictive Covenant Affecting Approximately 39 Acres of Land in Jefferson County, Illinois, to the State of Illinois, Department of Conservation.

E2. Release of a Restrictive Covenant Affecting Approximately 20.99 Acres of Land on Wheeler Reservoir in Morgan County, Alabama, to the City of Decatur.

E3. Amendment to the Kentucky Reservoir Plan to grant a 25-Year Easement Affecting Approximately 6.8 Acres of Land in Marshall County, Kentucky, to the Kentucky Department of Fish and Wildlife Resources.

E4. Sales of Noncommercial, Nonexclusive Permanent Easements Affecting 0.32 Acre of Tellico Lake Shoreline in Loudon and Monroe Counties, Tennessee.

F—Unclassified

F1. Revisions in Organizational Responsibilities for TVA's Security Clearance and Classified Information Program.

F2. Contract with Babcock and Wilcox for the Cumberland Fossil Plant, Units 1 and 2, Subject to Final Review Prior to Execution.

F3. Contract with F.E. Moran, Inc., Special Hazard Systems for a System-Wide Fire Protection Upgrade, Subject to Final Review Prior to Execution.

F4. Filing of Condemnation Cases.

Information Items

1. Public Auction Sale of Beaver Creek Reservoir Land.
2. Public Auction Sale of Clear Creek Reservoir Land.

CONTACT PERSON FOR MORE INFORMATION: Ron Loving Vice President, Governmental Relations, or a member of his staff can respond to requests for information about this meeting. Call (615) 632-6000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 898-2999.

Dated: May 18, 1994.

William L. Osteen,

Associate General Counsel and Assistant Secretary.

[FR Doc. 94-12595 Filed 5-19-94; 9:13 am]

BILLING CODE 8120-08-M

federal register

Monday
May 23, 1994

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 173 and 573

Secondary Direct Food Additives Permitted in Food for Human Consumption; Food Additives Permitted in Feed and Drinking Water of Animals; Aminoglycoside 3′-Phosphotransferase II; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 173 and 573

[Docket No. 93F-0232]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Food Additives Permitted in Feed and Drinking Water of Animals; Aminoglycoside 3'-Phosphotransferase II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aminoglycoside 3'-phosphotransferase II (APH(3')II) as a processing aid in the development of new varieties of tomato, oilseed rape, and cotton. APH(3')II is a protein encoded by the kanamycin resistance (*kan*^{r}) gene. This action is in response to a petition filed by Calgene, Inc.

DATES: Effective May 23, 1994; written objections and requests for a hearing by June 22, 1994.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202-254-9523.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

A. Regulatory History

In accordance with 21 CFR 10.85, Calgene, Inc., submitted to FDA on November 26, 1990, a request for advisory opinion regarding whether the *kan*^{r} gene, a selectable marker, may be used in the production of genetically engineered tomato, cotton, and oilseed rape plants intended for human food and animal feed uses (*kan*^{r} Gene: Safety and use in the production of genetically engineered plants, Docket Number 90A-0416). In the **Federal Register** of May 1, 1991 (56 FR 20004), FDA announced that the request had been received and solicited comments from interested persons. The data submitted to the agency with the request for advisory opinion and the comments received were made available to the public at the Dockets Management Branch.

Subsequent to the submission of the request for advisory opinion, FDA published its "Statement of Policy: Foods Derived From New Plant Varieties" (the 1992 policy statement) in the **Federal Register** of May 29, 1992 (57 FR 22984). This policy statement clarified FDA's interpretation of the Federal Food, Drug, and Cosmetic Act (the act) with respect to human foods and animal feeds derived from new plant varieties, including plants developed by new methods of genetic modification such as recombinant deoxyribonucleic acid (DNA) techniques.

In the 1992 policy statement, FDA stated that the postmarket authority under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) would continue to be the primary legal tool for ensuring the safety of whole foods derived from genetically modified plants. FDA also noted that under the statutory definition of "food additive" in section 201(s) of the act (21 U.S.C. 321(s)), the transferred genetic material and the intended expression products could be subject to regulation as food additives, if such material or expression products were not generally recognized as safe (GRAS) (57 FR 22984 at 22990). FDA further stated that the agency would use its food additive authority to the extent necessary to ensure public health protection (such as when an intended expression product in a food differs significantly in structure, function, or composition from substances found currently in food) (57 FR 22984 at 22990).

The 1992 policy statement specifically discussed selectable markers that provide antibiotic resistance in product selection and development. With such markers, both the antibiotic resistance gene and the gene product, unless removed, are expected to be present in foods derived from such plants. FDA stated:

> Selectable marker genes that produce enzymes that inactivate clinically useful antibiotics theoretically may reduce the therapeutic efficacy of the antibiotic when taken orally if the enzyme in the food inactivates the antibiotic. FDA believes that it will be important to evaluate such concerns with respect to commercial use of antibiotic resistance marker genes in food, especially those that will be widely used. (See 57 FR 22984 at 22988.)

Subsequently, in January 1993, Calgene requested that FDA convert its request for advisory opinion to a food additive petition under section 409 of the act. FDA then announced in the **Federal Register** of July 16, 1993 (58 FR 38429), that a food additive petition (FAP 3A4364) had been filed by Calgene, Inc., 1920 Fifth St., Davis, CA 95616, proposing that the food additive regulations be amended to provide for the safe use of APH(3')II as a processing aid in the development of new varieties of tomato, oilseed rape, and cotton.

After completing its review of the data submitted by Calgene, FDA convened a public meeting of its Food Advisory Committee on April 6 through 8, 1994, to undertake a scientific discussion of

the agency's approach to evaluating the safety of whole foods produced by new biotechnologies; a genetically modified tomato developed by Calgene containing the *kan*^{r} gene served as an example and focus of the discussion. The membership of the standing committee was supplemented with temporary members and consultants to the committee, representing scientific disciplines appropriate to the evaluation of foods derived from new plant varieties developed using recombinant DNA techniques.

At the meeting, Calgene presented a summary of the data they considered adequate to show safety of the tomato, and FDA presented its evaluation of the data. The committee was asked to comment on the approach used by FDA to evaluate whole foods and specifically, on the approach used for the Calgene tomato (Ref. 1). During committee discussion of the Calgene and FDA presentations, the committee members generally expressed the view that the approach used by FDA to evaluate the safety of the tomato, including the safety of the *kan*^{r} gene, was appropriate and that all relevant scientific questions had been adequately addressed.

In regard to the use of the *kan*^{r} gene, Calgene and the agency presented, and the committee discussed, such issues as the potential allergenicity of APH(3′)II and the potential for ingested APH(3′)II to inactivate orally administered antibiotics. Most of the discussion concerning the *kan*^{r} gene focused on the potential transfer of the gene to microorganisms in the gastrointestinal (GI) tract or in the environment. In evaluating Calgene's food additive petition for the use of the *kan*^{r} gene product, APH(3′)II, in the development of new varieties of tomato, oilseed rape, and cotton, FDA has considered the committee's discussions and recommendations on this subject, which are summarized in section III.B.3. of this document.

B. Scope of the Regulation

Having completed its evaluation and having considered the deliberations of the Food Advisory Committee, the agency is amending the food additive regulations to permit the use of APH(3′)II in the development of genetically modified tomatoes, oilseed rape, and cotton intended for food use. Only the translation product of the *kan*^{r} gene, APH(3′)II, and not the gene itself, is being regulated as a food additive. As the 1992 policy statement indicated, FDA does not anticipate that transferred genetic material (deoxyribonucleic acid (DNA)) would itself be regulated as a food additive (57 FR 22984 at 22990). DNA is present in the cells of all living organisms, including every plant and animal used for food by humans or animals, and is efficiently digested (Ref. 2). In this respect, the DNA that makes up the *kan*^{r} gene does not differ from any other DNA and does not itself pose a safety concern as a component of food.

This final rule is being promulgated after consideration of the issues relating to the safety of the use of APH(3′)II in the selection of transgenic plants. In addition, as noted above, because of the property of the *kan*^{r} gene to confer antibiotic resistance, the agency has considered the possibility that the gene might be transferred to other organisms (discussed in section III.B. of this document).

Potential safety issues specific to particular food products that contain the *kan*^{r} gene are not addressed by the agency in this document because such issues are beyond the scope of this rulemaking. For example, issues associated with other co-transferred DNA sequences, including other genes intended to impart specific traits, and issues related to potential genetic instability are not addressed because such issues will vary with specific products.

Developers of new plant varieties are responsible for addressing potential safety issues associated with specific food products resulting from the transfer of genetic materials and for ensuring the safety of the food products that they market. The policy statement contains a "Guidance to Industry" section (57 FR 22984 at 22991) that outlines an approach for the safety evaluation of foods derived from transgenic plants and suggests that the agency be consulted, as needed, to resolve critical issues.

As noted, issues related to genetic instability are not addressed because such issues are not unique to the *kan*^{r} gene but apply to any transferred genetic material irrespective of the transfer techniques used. Genetic instability could arise as a result of insertion of multiple copies of a given construct, especially if insertion occurs at multiple loci. Recombinations of the transferred DNA could cause deletions, duplications, or rearrangements within the plant genome (Ref. 3). Hence, in the 1992 policy statement, the agency noted that the genetic stability of a new plant variety is an important safety consideration and further stated that, "Factors that favor stability include a minimum number of copies of the introduced genetic material, and insertion at a single site." (57 FR 22984 at 23004).

In developing new plant varieties, developers are therefore responsible for following good manufacturing and good agricultural practices to ensure that they have developed a genetically stable transgenic plant. As a practical matter, this would ordinarily include using such techniques as segregation and Southern blot analysis to ensure that new plant varieties chosen for development have the new genetic material inserted into a single locus and that the number of copies of inserted DNA at a given site is limited to the minimum sufficient to achieve the intended effect.

C. Determination of Safety

Under section 409(c)(3)(A) of the act, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d sess. (1958)). FDA has incorporated this concept of safety into its food additive regulations. Under 21 CFR 170.3(i), a food additive is "safe" if "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

The agency has reviewed the data and studies submitted in the request for advisory opinion, material that was submitted subsequent to the conversion of the request for advisory opinion to a food additive petition, the deliberations of the Food Advisory Committee that took place at the April 1994 meeting, as well as other information in its files. In addition, the agency has considered the comments that were received in response to the **Federal Register** notice announcing receipt of the request for advisory opinion. The comments are addressed in section IV. of this document. As discussed below, FDA has concluded, based upon its review, that the use of aminoglycoside 3′-phosphotransferase II is safe for use as a processing aid in the development of new varieties of tomato, oilseed rape, and cotton intended for food use.

II. Use of the *kan*^{r} Gene As a Selectable Marker in Transgenic Plants

A Background

Developers have for many years used plant breeding techniques to introduce desirable genetic traits into new varieties that can be used in agriculture. Traditionally, breeders have relied on selection of mutants and on hybridization between different varieties of the same species to achieve this goal. More recently, recombinant DNA techniques (commonly referred to as "genetic engineering" techniques) have come into use to generate new plant varieties with desirable characteristics. Recombinant DNA techniques involve the isolation, and subsequent introduction into a host plant, of discrete DNA segments containing the gene(s) of interest. This introduction of exogenous DNA into a cell, resulting in its acquisition of a new phenotype, is commonly referred to as "transformation," and transformed plants that contain genetic material derived from sources other than the host plant itself are called transgenic.

The desired gene(s) may be introduced into a host plant by one of several methods, including: (1) Direct DNA uptake by the plant cells mediated by chemical or electrical treatments; (2) microinjection of DNA directly into plant cells; (3) biolistics, or firing tiny particles coated with the DNA of interest into plant cells; and (4) the use of a bacterium, such as the soil bacterium *Agrobacterium tumefaciens*, as a vehicle to carry the DNA into plant cells. (For a discussion of these processes, see Ref. 4).

B. Need for a Selectable Marker

Transformation of plant cells by introducing exogenous DNA is an inefficient process and, in general, only a small proportion of cells will successfully take up, integrate, and express the new genetic material (Ref. 5). Further, the few cells that do so are not readily distinguishable from the vast majority of cells that do not. Therefore, developers of transgenic plants need a means to distinguish cells that are successfully transformed from those that are not. Selectable markers, such as the *kan*^{r} gene, perform this function.

The *kan*^{r} gene is linked to the gene (or genes) of interest and then this genetic material is inserted into plant cells. Because plant cells are sensitive to the antibiotic kanamycin, incorporation of the *kan*^{r} gene into cells and subsequent expression of APH(3')II provides a convenient method for selecting successfully transformed cells. *Kan*^{r} works as a marker because only successfully transformed cells (which contain both the *kan*^{r} and the desired genetic material) survive when grown in a kanamycin-containing medium. These cells are subsequently regenerated into transgenic plants.

C. Identity of the Additive

APH(3')II [1] (CAS Reg. No. 58943–39–8) is encoded by the *kan*^{r} gene, which was originally isolated as a component of transposon Tn5 [2] from the bacterium *Escherichia coli* (Refs. 6 and 7). APH(3')II is an enzyme with an apparent molecular weight of 25,000 that catalyzes the transfer of a phosphate group from adenosine 5'-triphosphate (ATP) to a hydroxyl group of aminoglycoside antibiotics (see below), thereby inactivating the antibiotics.

APH(3')II inactivates the aminoglycoside antibiotics neomycin, kanamycin, paromomycin, ribostamycin, gentamicins A and B, as well as butirosins (Refs. 8 and 9). Of the antibiotics that are inactivated by APH(3')II, only neomycin and kanamycin are currently approved for use in humans or animals in the United States (Refs. 10 and 11).[3]

The APH(3')II evaluated in this document is the enzyme whose synthesis is directed by the *kan*^{r} gene derived from transposon Tn5. This enzyme is not to be confused with enzymes that may be similarly named (e.g., a type I aminoglycoside phosphotransferase encoded by a gene isolated from transposon Tn601) or other bacterial enzymes (including acetyltransferases, nucleotidyltransferases, and phosphotransferases) that inactivate kanamycin and neomycin (Refs. 8 and 12).

D. Use and Intended Technical Effects

Aminoglycoside antibiotics exert their effect on bacteria by binding to bacterial ribosomes and inhibiting protein synthesis. Phosphorylation of the antibiotics by APH(3')II interferes with this binding and thus prevents the antibiotics from inhibiting protein synthesis (Ref. 13). In this way, cells that contain the *kan*^{r} gene and that express APH(3')II are rendered resistant to the action of the antibiotics. In plant cells, the antibiotics exert their effect on mitochondria and chloroplasts where protein synthesis takes place on ribosomes that resemble bacterial ribosomes (Ref. 14).

The proposed use of the *kan*^{r} gene and gene product APH(3')II is as a processing aid in the development of new varieties of tomato, cotton, and oilseed rape intended for food use. As discussed above, because transformation of plant cells is an inefficient process, the presence of APH(3')II and the consequent ability of the plant cells to grow in the presence of antibiotics is used to distinguish between transformed and nontransformed cells. Therefore, the intended technical effect of APH(3')II is to permit, in the early phases of development of genetically modified plants, the selection of transformants carrying the *kan*^{r} gene along with the genetic material of interest. However, APH(3')II has no intended technical effect in the final plant or final crop product.

III. Safety Evaluation

A. APH(3')II

Safety issues associated with APH(3')II can be divided into two areas: (1) Those associated with the direct effects of ingestion of the protein, including the possibility of allergenicity; and (2) those associated with the biological activity of APH(3')II (i.e., the effect of the enzyme on the therapeutic efficacy of orally administered antibiotics).

1. Direct Effects of Ingestion

Calgene provided evidence that APH(3')II is rapidly inactivated by stomach acid, is degraded by digestive enzymes, and is not modified by glycosylation (i.e., does not contain sugar molecules attached to the protein) when produced in the transgenic plants under consideration. In addition, Calgene noted that enzymes such as APH(3')II are heat labile. Thus, Calgene concluded that APH(3')II does not possess any of the characteristics associated with allergenic proteins such as proteolytic stability, glycosylation, or heat stability (Ref. 15). In April 1992, Calgene also conducted protein and DNA sequence comparisons using sequences in four separate databases (GenBank, EMBL, PIR 29, and Swiss-Prot) and established that APH(3')II does

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[1] Other names for this enzyme include neomycin phosphotransferase II (NPT II), neomycin phosphotransferase, and kanamycin phosphotransferase II.

[2] A transposon is a segment of DNA that is mobile and has the capacity to move from one site in the genome to another. Transposons vary in size and frequently contain, as does Tn5, antibiotic resistance genes in addition to genes coding for functions concerned with movement of the transposon.

[3] Gentamicin, which is used therapeutically, is composed of a complex mixture of the antibiotic substances produced by *Micromonospora purpurea* that contain primarily gentamicin C_1 (25 to 50 percent), gentamicin C_{1a} (10 to 35 percent), and gentamicins C_{2a} and C_2 (25 to 55 percent) (Ref. 10). Gentamicins A and B are at most minor components of the commercial drug. Thus, APH(3')II does not confer resistance to gentamicin that is used therapeutically (Ref. 12).

not have significant homology to any proteins listed as food allergens or toxins in these databases.

FDA agrees with Calgene that the characteristics of APH(3')II do not raise a safety concern. First, each whole food, on average, contains several thousands of different proteins (Ref. 16). As a class, proteins are rarely toxic (Ref. 17) and APH(3')II is not known to be toxic. Second, APH(3')II is a phosphorylating enzyme, and all plants and animals that are part of the food supply contain such phosphorylating enzymes without adverse consequences. Third, APH(3')II has been shown to be rapidly degraded under simulated gastric conditions (Refs. 18 through 21). Finally, the estimated dietary exposure to APH(3')II is very low (480 µg APH(3')II per person per day,[4] or 0.16 part per million in the diet, based on a 100-percent market share for tomatoes containing APH(3')II (Ref. 18)).

Based upon the available evidence, the agency believes that this protein does not possess any properties that would distinguish it toxicologically from other phosphorylating enzymes in the food supply. Further, because of the low exposure levels and normal digestibility of APH(3')II, the agency concludes that no limits other than good manufacturing practice are needed to ensure the safety of the petitioned use of APH(3')II (Ref. 20).[5]

2. Effects on the Therapeutic Efficacy of Orally Administered Antibiotics

a. *APH(3')II in human foods.* i. *Relevant source of APH(3')II.* Calgene considered whether APH(3')II could affect the therapeutic efficacy of orally administered aminoglycoside antibiotics. In doing so, Calgene stated that only APH(3')II from fresh tomatoes is relevant because it is the only form that is enzymatically active. Processed tomato products (such as processed whole tomatoes, chili, juice, pulp, paste, catsup, and soup) are subjected to temperatures in the range of 82 to 100 °C; these temperatures would be expected to inactivate the APH(3')II enzyme. For edible oils extracted from cottonseed and rapeseed, high temperature treatment, solvent extraction, and subsequent purification steps generally included in the processing of such oils would also be expected to inactivate APH(3')II.

FDA agrees that high temperature treatment denatures proteins and inactivates enzymes and therefore, processed products that contain tomatoes with the *kan*^{r} gene are unlikely to contain any enzymatically active APH(3')II. In addition, purified oils essentially do not contain protein; therefore, oils derived from transgenic cottonseed and rapeseed modified using the *kan*^{r} gene would not be expected to contain active or inactive APH(3')II (Refs. 18 and 23). Thus, FDA agrees that fresh tomatoes from plants developed using the *kan*^{r} gene are the only source of active APH(3')II.

ii. *Effect of APH(3')II in fresh tomatoes on the therapeutic efficacy of orally administered antibiotics.* Calgene performed several experiments intended to address whether APH(3')II consumed as a component of fresh tomatoes could render orally-administered kanamycin ineffective. These experiments were performed under simulated gastric and intestinal conditions (i.e., appropriate pH, reagent concentrations, temperature, and reaction times) chosen to reflect conditions expected in vivo. In some studies both tomato extract and nonfat milk were added to determine whether the presence of additional food-source proteins in the simulated gastric and intestinal fluids might slow the proteolytic degradation of APH(3')II by competition. After evaluating the loss of immunologically detectable APH(3')II, Calgene concluded that, under normal gastric and intestinal conditions, APH(3')II would be effectively degraded before the enzyme could inactivate kanamycin or neomycin and therefore, APH(3')II would not interfere with orally administered kanamycin or neomycin therapy. The results of Calgene's experiments were the same whether done in the presence or the absence of tomato extract and nonfat milk.

In addition, Calgene presented the results of in vitro degradation studies performed under simulated abnormal gastric conditions, such as may exist in patients treated with drugs that reduce stomach acidity. Calgene stated that these studies demonstrated that APH(3')II is not degraded in neutralized (pH 7.0) simulated gastric fluid and thus, APH(3')II may remain active in such abnormal gastric conditions. However, Calgene pointed out that, even under those conditions, APH(3')II would not be expected to inactivate orally administered kanamycin or neomycin because the concentration of ATP, which the enzyme requires to inactivate kanamycin and neomycin, would be limiting. In support of this contention, Calgene presented data from the published literature on ATP levels in fresh fruits and vegetables. Calgene then estimated ATP intake and calculated the fraction of neomycin that would be phosphorylated assuming that all of the available ATP reacted with the antibiotic. Under the worst-case situation (high intake of ATP-containing food, low dose of antibiotic) Calgene's calculations showed that only a small fraction (no more than 1.5 percent) of the antibiotic would be inactivated. Moreover, Calgene presented data that showed that no significant inactivation of kanamycin was observed during in vitro studies conducted with tomato extract containing APH(3')II and kanamycin over a 4-hour incubation period.

iii. *Agency conclusions.* The agency has evaluated the data and other information presented by Calgene (Refs. 18 through 21 and 24). FDA agrees that Calgene's in vitro digestion studies show that, as is the case for dietary protein in general, the biological activity of APH(3')II is destroyed during gastric and intestinal phases of digestion. Further, the agency has determined that any active APH(3')II that might remain would not significantly inactivate kanamycin or neomycin in the gut because the small amount of ATP in fruits and vegetables would limit the amount of antibiotic that could be phosphorylated. ATP is an extremely labile molecule that is susceptible to inactivation both by heat (e.g., cooking) and by enzymes, such as alkaline phosphatases (Ref. 25), that are found in the intestine. Because the ATP in meat, poultry, fish, and cooked vegetables would be broken down by cooking, the primary source of ATP in the gastrointestinal (GI) tract of patients would be uncooked fruits and vegetables. However, the amount of ATP in a variety of fruits and vegetables would provide enough ATP to inactivate only a small percentage of kanamycin or neomycin, even if one makes the conservative assumption that

[4] Because oils produced from transgenic cottonseed and rapeseed would not contribute APH(3')II to the human diet (see also section 2 below), the exposure estimate was derived exclusively for tomatoes. The agency made several conservative assumptions in arriving at the probable per capita exposure to APH(3')II of 480 µg/person/day. For example, FDA assumed that all tomatoes contain APH(3')II at a level of 0.1 percent of total protein although, of the two lines intended for commercialization by Calgene, one contains less than 0.01 percent and the other less than 0.002 percent of APH(3')II (as a percentage of total protein). Second, FDA included APH(3')II in processed products in its estimate although high temperature treatment used in the production of processed products would be expected to result in loss of enzymatic activity of APH(3')II. In summary, the exposure estimate represents a theoretical maximum rather than a realistic estimate of exposure to APH(3')II.

[5] A recently published study (Ref. 22) also showed that APH(3')II is rapidly degraded under simulated mammalian digestive conditions. In addition, in an acute mouse feeding study, the investigations showed that feeding highly exaggerated doses of purified APH(3')II caused no deleterious effects.

all of the ATP in these fruits and vegetables would survive the alkaline phosphatases in the intestines and would be available for catalytic phosphorylation of kanamycin or neomycin.

In addition, the agency has considered the patient population likely to be exposed to aminoglycoside antibiotics. Oral aminoglycosides are most commonly administered to either pre-operative patients (prior to bowel surgery) or patients with hepatic encephalopathy. Neither patient population would be expected to be ingesting tomatoes or any other fresh fruits and vegetables; therefore there is little or no risk of inactivating the oral antibiotic in these patients (Refs. 24 and 26). For these reasons, FDA concludes that the presence of APH(3')II in food will not compromise the therapeutic use of orally administered kanamycin or neomycin.

b. *APH(3')II in animal feed.* Calgene also considered the potential inactivation of neomycin that is used in animal feeds manufactured using cottonseed meal and rapeseed meal obtained from transgenic plants. The transgenic tomato was not considered because only small amounts of tomato and tomato byproducts are used in the animal feed industry. Further, neomycin is primarily used to treat calves and swine whereas tomato byproducts, to the extent that they are used in animal feed, are primarily used as ingredients in cattle diets (Ref. 27).

Calgene analyzed neomycin levels both in nontransgenic medicated cottonseed and rapeseed meals and in transgenic medicated cottonseed and rapeseed meals over a storage period of 56 days (considered a worst-case situation) and concluded that there was no significant inactivation of neomycin.

FDA reviewed the data submitted by Calgene and concludes that there was no significant difference with respect to neomycin stability between medicated cottonseed and rapeseed meals prepared from transgenic cottonseed and rapeseed containing APH(3')II, and appropriate controls (Ref. 28). Therefore, the agency concludes that transgenic strains of cottonseed and rapeseed containing APH(3')II have no apparent untoward effect regarding the stability of neomycin and that the therapeutic efficacy of neomycin in animal feed will not be affected. The agency also considers this conclusion applicable to other aminoglycoside antibiotics, e.g., gentamicin, when orally administered.

B. The Kan^r Gene

The agency also evaluated issues relevant specifically to the safety of the use of the *kan^r* gene in tomato, oilseed rape, and cotton. In particular, FDA evaluated the potential for horizontal transfer of the gene and subsequent expansion of the population of antibiotic-resistant pathogens. The agency evaluated whether efficacy of oral antibiotic treatment of humans or animals could be compromised by consumption of food containing the *kan^r* gene either because of the development of resistant intestinal microflora in humans and animals or because the cells lining the intestinal lumen might become transformed. In addition, the agency considered the possible transfer of the *kan^r* gene from transgenic plants to soil microorganisms and expansion of the antibiotic-resistant bacterial population.

1. Potential Transfer of the *kan^r* Gene to Intestinal Microorganisms and Cells Lining the Intestinal Lumen

Calgene presented theoretical and experimental evidence to demonstrate that the potential for compromise of antibiotic therapy by horizontal transfer of the *kan^r* gene to gut microorganisms or intestinal epithelial cells is not of significant concern. Calgene considered the sources of the *kan^r* gene, the role digestion plays in degrading DNA, and possible DNA transfer mechanisms.

a. *Relevant source of the kan^r gene available for transformation.* Calgene considered potential transfer of the *kan^r* gene only from fresh tomatoes because processing is expected to inactivate the *kan^r* gene in processed tomato products and in food products derived from cotton and oilseed rape. The *kan^r* gene is not expected to survive procedures used to process tomatoes because heating processes, such as those used in commercial processing, can directly degrade DNA or can damage DNA by releasing cellular DNA-degrading enzymes.

The *kan^r* gene is also not expected to survive the process of oil production from cottonseed and rapeseed. Mechanical grinding or flaking of oilseeds during the production of oils and meals from oilseeds is expected to liberate degradative enzymes normally present within the cell that would degrade the *kan^r* gene. In addition, oil processing also includes high temperatures and solvent extractions, both of which would be expected to inactivate the *kan^r* gene. Moreover, because DNA is hydrophilic, it is unlikely to fractionate into oil, which is hydrophobic, during the extraction of oil from cottonseed and rapeseed. Therefore, intact DNA, including the *kan^r* gene, is not expected to survive the production of oils and animal feeds from cottonseed and rapeseed.

b. *Effect of digestion on the availability of the kan^r gene for possible transformation.* Calgene demonstrated that most if not all of the DNA comprising the *kan^r* gene ingested by humans will be degraded in the stomach and upper small intestine before it reaches the lower small intestine, cecum, and colon, and would be unavailable for potential transformation of gut microorganisms. Calgene estimated that 99.9 percent of fresh tomato DNA would be digested to fragments smaller than 1,000 base pairs. This estimate was based on in vitro studies that found that only 0.1 percent of DNA could be detected as fragments of 1,000 base pairs or longer after exposure to stomach-simulating fluids for 10 minutes and to intestinal-simulating fluids for another 10 minutes. Thus most of the DNA remaining after digestion would be smaller than the *kan^r* gene which is about 1,000 base pairs long.

Regarding animal feed, food-producing animals consume primarily processed forms of cottonseed and rapeseed, in which, as discussed above, the *kan^r* gene is not expected to remain intact. In addition, researchers have shown that nucleic acids introduced into the rumens of calves, or incubated with calf, sheep, or cow rumen contents in vitro, were rapidly and completely degraded to nucleotides and nucleosides (Ref. 29).

c. *Calculation of worst-case transformation frequencies.* In its submission, Calgene addressed the potential for horizontal transfer of the *kan^r* gene. Natural transformation, i.e., the uptake and incorporation into the genome of free DNA, is known to occur in some bacterial species. This is the only possible mechanism by which intestinal microflora could take up free DNA (Ref. 30). However, none of the species known to be present in the GI tract has been found capable of acquiring exogenous DNA by natural transformation. Nonetheless, to consider the worst-case scenario, Calgene assumed that all microbes in the intestine would be able to take up and incorporate exogenous DNA at a frequency found for certain species of the genus *Streptococcus*. Calgene noted that although the firm developed its transformation model for certain *Streptococcus* species, they are not aware of any information indicating that *Streptococcus* species found in the GI tract can be naturally transformed.

To undergo natural transformation, the recipient bacterium must be transformation-competent, i.e., ready to take up DNA. As noted, none of the bacterial species that occur in the GI tract is known to be capable of becoming transformation-competent. In addition, the genome of a recipient bacterium should contain DNA homologous to the incoming DNA (Refs. 31 and 32). Because the genomes of intestinal *Streptococci* or other intestinal bacteria are not expected to exhibit homology to the DNA constructs containing the *kan*^{r} gene[6], Calgene assumed that the *kan*^{r} gene could only undergo "illegitimate" recombination, a process that does not require significant DNA homology. Calgene noted that illegitimate recombination occurs in microorganisms at a much lower rate than homologous recombination.

Under the foregoing worst-case assumptions, Calgene estimated that if a person consumes fresh tomatoes at the 90th percentile level (i.e., eats more tomatoes than 89 percent of the individuals in the population), the transformation frequency of the intestinal microorganisms with the *kan*^{r} gene will be approximately 3×10^{-15} transformants per day. This transformation frequency is more than 5 orders of magnitude less than the frequency of mutation to kanamycin resistance per bacterial replication, i.e., 10^{-9} (Ref. 12). Thus, Calgene showed that for every 300,000 bacteria that mutate to kanamycin resistance per replication (generally a matter of hours), there would be, at most, under worst-case conditions, one kanamycin-resistant bacterium per day added to that number due to transformation.

Calgene stated that the potential for food-producing animals to experience decreased efficacy of antibiotic therapy as a result of pathogenic intestinal microflora incorporating and expressing the *kan*^{r} gene would be similar to that described for humans, i.e., equally improbable. In reaching this conclusion, Calgene relied on the finding that DNA is rapidly and completely digested in the gut of food animals (Ref. 29) and on the contention that the worst-case transformation scenario described above for human gut microorganisms also applies to microorganisms found in the gut of food-producing animals.

[6]One population that does contain DNA segments homologous with part of the *kan*^{r} construct is *E. coli*, because the *kan*^{r} construct contains part of an *E. coli* gene. Although *E. coli* constitutes one of the predominant species of aerobic GI tract bacteria, *E. coli* is not transformation-competent under conditions that prevail in the GI tract (Ref. 33). Thus, transformation of *E. coli* due to homologous recombination is not an issue.

With respect to epithelial cells lining the intestinal lumen, Calgene provided information that no transformation of human epithelial cells has been demonstrated in vivo (Ref. 2). In addition, even if transformed, intestinal epithelial cells are terminally differentiated (i.e., do not divide) and have a relatively short life span (Ref. 34), and thus would continually be shed and replaced by nontransformed cells.

2. Potential Transfer of the *kan*^{r} Gene to Soil Microorganisms

Calgene also considered the possibility that the *kan*^{r} gene might be transferred to soil microorganisms, thereby increasing the level of antibiotic-resistant organisms in the environment. Calgene pointed out that the only plausible mechanism by which gene transfer could occur between plants and bacteria is through natural transformation. Taking this mechanism into consideration and using worst-case assumptions similar to those discussed above for intestinal microorganisms, Calgene calculated that, at worst, kanamycin-resistant transformants resulting from plant DNA left in the fields would represent not more than one in 10 million of the existing kanamycin-resistant soil population.

3. Food Advisory Committee Discussions Regarding Potential Horizontal Transfer of the *Kan*^{r} Gene

As part of its discussion of the scientific issues related to the evaluation of Calgene's genetically engineered tomato, the Food Advisory Committee discussed the possibility that the *kan*^{r} gene might be transferred to microorganisms in the GI tract and in the environment (Ref. 1).

The committee members concluded that transfer of the *kan*^{r} gene consumed as a component of tomatoes to microorganisms in the GI tract was highly unlikely based on published data in the scientific literature. Similarly, the committee members judged that the potential for transfer of the *kan*^{r} gene from plants to microorganisms in the environment is highly unlikely based on the members' knowledge of mechanisms of gene transfer. In addition, members of the committee pointed out that the rate at which such transfer could take place, if at all, was of so small a magnitude that, coupled with the high prevalence of kanamycin resistant organisms already present in the environment, it would not cause a significant environmental impact.

Some members of the committee, while convinced by the information presented at the meeting that the transfer of the *kan*^{r} gene from tomato plants to microorganisms in the soil was improbable, expressed concern regarding the use of the *kan*^{r} gene in other crops that may be grown on a wide scale. In addition, some committee members were concerned that a determination of safety with regard to the use of *kan*^{r} gene in Calgene's tomato might signal to producers that it is now permissible to use the *kan*^{r} gene in other crops. In light of such concerns, these committee members advised that use of the *kan*^{r} gene in other crops should be evaluated on a case-by-case basis.

4. Agency Conclusions

The agency has considered the recommendations of the members of the Food Advisory Committee. The agency agrees that the potential transfer of the *kan*^{r} gene, as well as other antibiotic resistance marker genes, from crops to microorganisms should be evaluated on a case-by-case basis. As noted, Calgene petitioned for the use of the *kan*^{r} gene product, APH(3')II, in the development of genetically engineered cotton and oilseed rape in addition to tomato. As discussed below, the agency has evaluated data and information concerning horizontal transfer of the *kan*^{r} gene from its use in all three crops. This is consistent with the committee's advice that safety of the use of the *kan*^{r} gene be evaluated on a case-by-case basis. In addition, Calgene's petition seeks to amend the food additive regulations to permit the use of APH(3')II only in tomato, cotton, and oilseed rape; approval of Calgene's petition would not mean that developers could use the *kan*^{r} gene in crops other than those identified in the petition.

FDA has also evaluated the information submitted by Calgene and has determined that the probability of transfer of the *kan*^{r} gene to gut microflora is remote and that even under worst-case conditions, the number of microorganisms that would be converted to kanamycin resistance is negligible when compared to the reported prevalence of gut microflora that are already resistant to kanamycin (Ref. 35). This conclusion applies to both humans and animals. The agency has determined that exposure to foods that contain the *kan*^{r} gene will not compromise the efficacy of antibiotic treatment because the likelihood of increasing the number of antibiotic resistant microorganisms is extremely low. Further, the agency has determined that there is no evidence that free DNA containing the *kan*^{r} gene, even if present, can transform cells lining the GI tract (Ref. 2).

FDA has also evaluated the information submitted by Calgene concerning soil microorganisms and agrees with Calgene that there would be no increase in kanamycin-resistant soil microorganisms because it is highly unlikely that the *kan*^{r} gene could move from the plant genome into soil microorganisms via horizontal gene transfer. Further, the agency has determined that, even if such transfer could occur, the rate at which it could occur is such that it would not result in a detectable increase over the existing background population of kanamycin-resistant bacteria (Ref. 36). Based on the foregoing, FDA has concluded that the use of the *kan*^{r} gene does not pose safety concerns in terms of increase in the population of antibiotic-resistant pathogens due to the potential for horizontal transfer of the gene.

IV. Response to Comments

FDA received 47 comments on Calgene's request for an advisory opinion on the use of the *kan*^{r} gene in the development of new varieties of tomato, oilseed rape, and cotton plants. Comments were received from members of academia, industry and industry-related organizations, State and Federal agencies, environmental groups and other nonprofit organizations, and individual consumers. Additionally, several comments on the agency's 1992 policy statement addressed the use of the *kan*^{r} gene.

Most of the comments supported the use of the *kan*^{r} gene in crop development, stating that there were no health or environmental issues precluding its use. Several comments expressed opinions on a wide range of issues including regulatory approaches for genetically engineered foods, concerns relating to human and animal food safety, and to the environmental effects of the *kan*^{r} gene, and whether foods containing the *kan*^{r} gene and APH(3')II should be specially labeled.

A. Regulatory Issues

Some comments stated that it was not appropriate for FDA to evaluate the safety of the *kan*^{r} gene and APH(3')II under an advisory opinion and that the *kan*^{r} gene and APH(3')II should be treated as food additives by FDA. FDA has discussed above the basis for its decision not to regulate the DNA that makes up the *kan*^{r} gene itself as a food additive. Further, in light of Calgene's conversion of its request for advisory opinion on the use of the *kan*^{r} gene to a food additive petition, the comment concerning the regulation of APH(3')II as a food additive no longer requires a response

B. Food Safety

Several comments stated that the presence in food of APH(3')II raised no food safety concerns whatsoever. Others questioned whether Calgene had supplied adequate data to ensure the safety of the *kan*^{r} gene and gene product, APH(3')II, when present in food. The substantive questions raised are discussed in sections IV.B.1 through 5 of this document

1. Glycosylation

Two comments stated that APH(3')II might be glycosylated (i.e., might contain sugar molecules attached to the protein via the amino acid asparagine (N-linked) or via the amino acids serine, threonine, or hydroxyproline (O-linked)) when produced in tomatoes or other plants and, therefore, might become a food allergen. One of the comments asserted that for this reason, Calgene should be required to test whether APH(3')II is glycosylated. The comments, however, did not provide any information showing that glycosylated APH(3')II is likely to be, or is, allergenic.

At this time, FDA is unaware of any practical method to predict or assess the potential for new proteins in food to induce allergenicity. Although many food allergens that have been characterized at a structural level are glycosylated (Ref. 37), the agency is not aware of any information on structural or other properties of glycosylated proteins that would be predictive of their allergenicity. As noted, the comments did not provide such information. Moreover, glycosylated proteins are widespread in food. For these reasons, glycosylation is not a useful positive predictor of a potential allergenic effect. Accordingly, FDA did not request that Calgene determine whether APH(3')II is glycosylated.

Nevertheless, in a submission dated October 24, 1991, entitled "Response to Public Comments," Calgene addressed whether APH(3')II is likely to be glycosylated and concluded that it is not. Calgene noted that APH(3')II lacks the amino terminal sequence of amino acids (commonly referred to as a "signal peptide") that is necessary to direct the protein into the cellular compartments where glycosylation occurs. Calgene also asserted that the unchanged molecular weight of APH(3')II in plants (relative to the molecular weight of bacterial APH(3')II, which is not glycosylated) supports the conclusion that APH(3')II is not glycosylated in plants. Finally, Calgene stated that the amino acid sequence (asparagine-X-serine/threonine) that is required to direct N-linked glycosylation to specific asparagine moieties is not present in APH(3')II. (Calgene noted that a corresponding argument for the lack of the appropriate amino acid sequence to direct O-linked glycosylation cannot be made because the sequences that direct O-linked glycosylation have not been defined.)

FDA has considered the information and arguments submitted in the comments and Calgene's response and has concluded that the available evidence indicates that APH(3')II is not glycosylated in plants. However, even if glycosylation had been demonstrated, FDA emphasizes that glycosylation alone does not necessarily establish that APH(3')II is likely to produce an allergenic response because the positive predictive value of glycosylation with respect to the potential for inducing allergenicity has not been demonstrated

2. In Vitro Digestibility Studies

In its original submission, Calgene presented the results of in vitro digestibility studies that demonstrated that APH(3')II enzymatic activity is rapidly decreased in simulated gastric fluid and in simulated intestinal fluid.

One comment asserted that Calgene should provide a more thorough study of degradation of APH(3')II in the digestive tract because the conditions of the in vitro digestibility study submitted by Calgene did not fully mimic the complex environments of the human gut. The comment further asserted that it was not clear whether the digestibility data also apply to neonates and to people with coeliac disorders or ulcers who can absorb peptides and intact proteins through their intestines. The comment noted that the applicability of the data to neonates would be of special importance should *kan*^{r} be used in soybeans because soy protein is a major component of some infant formulas. Importantly, however, the comment presented no information to provide a basis for concluding that the absorption of APH(3')II occurs, or that if it does, such absorption presents a health concern greater than that posed by the absorption of any other protein in the diet.

As discussed above, FDA has evaluated the studies presented by Calgene to demonstrate the normal digestibility of the enzyme and concurs with Calgene's conclusion that APH(3')II is rapidly degraded under normal conditions in the GI tract. Therefore, FDA believes that the intestinal transfer of intact or large fragments of APH(3')II is not likely to occur in individuals with normal GI tracts.

In regard to the possibility of increased intestinal absorption of proteins in neonates and individuals with special conditions (e.g., ulcers), FDA has concluded that there is no reason to expect that absorption of the intact or partially digested APH(3′)II protein would present a safety problem different from absorption of any other protein in the diet. As discussed above, proteins, as a class, are rarely toxic. Furthermore, APH(3′)II is a phosphorylating enzyme and does not contain any properties that would distinguish it toxicologically from any other phosphorylating enzymes that historically have been part of the food supply without adverse consequences. Finally, because Calgene did not petition FDA for the use of APH(3′)II in soybeans, it is not necessary to address the comment concerning the applicability of Calgene's digestibility data to neonates fed soybean-derived formulas.

3. Copy Number of the *kan*^{r} Gene and Expression Level of APH(3′)II

In its submission of November 26, 1990, Calgene stated that it did not intend to commercialize lines that contained more than 10 copies of the *kan*^{r} gene. In addition, Calgene also declared that, in tomatoes, the APH(3′)II level would be no more than 0.1 percent of the total protein of the tomato and that processing procedures would destroy APH(3′)II in processed tomatoes and edible oils extracted from cottonseed and rapeseed.

One comment asserted that Calgene inadequately described the methods by which it would ensure that no lines with greater than 10 copies of the *kan*^{r} gene would be marketed. The comment further asserted that many of the analyses offered by Calgene to prove the safety of the *kan*^{r} gene depend on estimates of the number of genes per cell and that, if the company cannot ensure this relatively low level of gene incorporation, many of its safety arguments are undermined. The comment, however, did not identify which of Calgene's safety analyses depended on estimates of the numbers of genes per cell.

The comment may have been referring to Calgene's assumption that each plant cell would contain 10 copies of the gene when it calculated a worst-case frequency of transformation of microorganisms with the *kan*^{r} gene that would result from use of the gene in transgenic plants. However, the agency notes that the outcome of those calculations, i.e., Calgene's conclusion that the transformation frequency of microorganisms with the *kan*^{r} gene is insignificant, would not change had Calgene assumed much higher gene copy numbers in its calculations. Therefore, FDA's safety assessment does not depend on precise estimates of gene copy number. Nor does the comment provide a basis for concluding that it is necessary to have precise methods for ensuring that no plants with more than 10 copies of the gene will be marketed.

A second comment maintained that Calgene provided an inadequate description of the quality control and assurance procedures the company would use to ensure that APH(3′)II would be kept to no more than 0.1 percent of total protein of the tomato, and that a number of the company's safety analyses rely on the amount of APH(3′)II in the food. The comment, however, did not identify which of Calgene's safety analyses relied on estimates of the concentration of APH(3′)II in the food.

FDA has determined that there is no need to set a tolerance for the amount of APH(3′)II that will be consumed because the agency knows of no reason why this protein would have any properties that would distinguish it toxicologically from any other phosphorylating enzymes in the food supply. Also, as discussed above, APH(3′)II will not affect efficacy of orally administered antibiotics because APH(3′)II is rapidly digested under normal conditions in the GI tract, and even in abnormal gastric conditions where APH(3′)II may not be rapidly digested, the amount of ATP available in food would allow only a small proportion of kanamycin and neomycin to be inactivated. Therefore, the agency concludes that there is no need to require quality control and assurance procedures to ensure that the APH(3′)II level will be no more than 0.1 percent of the total protein in commercial tomato varieties.

A third comment argued that Calgene did not provide data to establish that APH(3′)II would not be present after tomato processing and after extraction of edible oils.

The agency's exposure estimates included an assumption that APH(3′)II would be present in both processed tomatoes and fresh tomatoes even though the high temperatures involved in processing inactivate enzymes and therefore, processed tomato products are unlikely to contain enzymatically active APH(3′)II (Ref. 18). In addition, well-established processing procedures used to extract edible oils from oilseed crops do not extract significant amounts of protein (Ref. 23). Therefore, exposure to APH(3′)II obtained from rapeseed oil and cottonseed oil would be negligible (Ref. 18). The comment did not present any information to contradict FDA's analysis and conclusion on this point.

4. The Potential for Side Effects From Consumption of Genetically Engineered Foods

One comment asked whether there might be side effects from consumption of genetically engineered foods, and if so, whether these side effects would be short term or long term. Another comment noted that food plants and humans exhibit complex and unpredictable behavior and that therefore, the safety of a food substance should be based on thoughtfully gathered empirical evidence.

The comments did not point to any specific side effects of genetically engineered foods. FDA has evaluated the safety of APH(3′)II and has determined that it is safe for its proposed use. This safety assessment is in fact based on empirical evidence, such as the structure and function of APH(3′)II, the low level at which APH(3′)II occurs in foods, the digestibility of APH(3′)II, and the inability of APH(3′)II to interfere with clinically useful antibiotics under usual conditions of use for the antibiotics.

5. Relevance of Clinical Studies

Several comments noted that a National Institutes of Health (NIH) gene therapy trial in which cancer patients were infused with cells containing the *kan*^{r} gene, and which was cited by Calgene as strong evidence for the safety of the *kan*^{r} gene, provides little information concerning the safety of the *kan*^{r} gene and APH(3′)II in food. One comment also noted that the combination of data from the in vitro studies and the gene therapy study was an inadequate basis for a safety determination of the *kan*^{r} gene and APH(3′)II in food that millions of people might eat.

In determining that APH(3′)II is safe for its proposed food additive use, FDA did not rely on the NIH gene therapy trial. However, FDA does believe that the in vitro degradation data provide important information that should be and was considered by the agency as part of its overall safety assessment of the *kan*^{r} gene and APH(3′)II, as discussed earlier in this document.

C. Possible Effect on Clinical Efficacy of Orally Administered Kanamycin or Neomycin

Several comments questioned whether the presence of APH(3′)II in tomatoes or other foods might compromise the clinical efficacy of orally administered kanamycin or

neomycin. One comment noted that Calgene claimed that at most only 76,800 people annually were administered kanamycin or neomycin orally, and argued that those people deserved not to be put at risk. The comment further requested that Calgene be required to perform animal studies on the effects of ingestion of APH(3')II on the efficacy of orally administered kanamycin and neomycin. The comment asserted that if APH(3')II were shown to compromise clinical efficacy of kanamycin or neomycin, food containing APH(3')II should be appropriately labeled.

Other comments observed that ingested APH(3')II would not impair the efficacy of orally administered kanamycin and neomycin, that these antibiotics are rarely administered orally, and that the *kan*^{r} gene is therefore a good choice as a selectable marker gene.

FDA agrees with Calgene that kanamycin and neomycin are rarely administered orally. The primary clinical role for orally administered neomycin, and to a lesser extent kanamycin, is cleansing the bowel of microbes prior to bowel surgery. This use is relatively minor because of severe side effects (auditory nerve damage and kidney damage) that may result from the antibiotic that is absorbed from the GI tract (Ref. 38).

As discussed above, for most individuals receiving oral kanamycin or neomycin, APH(3')II will be inactivated by the acidic environment of the stomach and degraded by the digestive enzymes present in the GI tract. More important, even for patients receiving simultaneous treatment to reduce stomach acidity, the amount of ATP available from food would allow, at most, only a small fraction of kanamycin or neomycin to be inactivated. The comment advocating animal studies did not contradict directly or indirectly FDA's analysis concerning the inactivation and degradation of APH(3')II or the information concerning ATP levels. FDA has therefore determined that the presence of APH(3')II in food will not compromise therapy with orally administered kanamycin or neomycin. On this basis, FDA has concluded that neither animal studies on the effects of ingestion of APH(3')II on the efficacy of the antibiotics, nor special labeling of foods containing APH(3')II for patients receiving orally administered kanamycin or neomycin, are necessary.

D. Fate of the kan^r *Gene in the Environment*

1. Potential Transfer of the *kan*^{r} Gene From Crops to Microorganisms

One comment posited a connection between "the prophylactic use of antibiotics [resulting] in antibiotic-resistant bacteria reaching the human population" with a health risk from the possible addition of up to "10 antibiotic genes [sic] in most of the cells of major crops." The comment agreed with Calgene's documentation that the widespread use of antibiotics has led to an increase in antibiotic-resistant bacteria in the environment, but went on to postulate that this was evidence that introducing antibiotic-resistance genes into plants has human health implications.

The comment further asserted that the "scientific question is whether the resistance genes in the crops can be transferred by any mechanism [to] organisms that might be human pathogens," and that the company should be required experimentally to "determine the rates of gene transfer to soil bacteria from plant debris, the persistence or selection of organisms containing such genes in soil ecosystems, and other important factors in the assessment of the likelihood of releases compromising the use of antibiotics." The comment noted that Calgene analyzed these issues "in some detail," but with "arm chair calculations, most based on extrapolations from experiments done with other organisms under other circumstances."

A second comment noted that Calgene had supplied information that three kinds of bacteria, with and without plasmids [7] carrying antibiotic resistance genes, had little effect on several measures of soil ecosystems, but wrote that the "relevance of experiments on bacteria to releases of plants is marginal, at best." A third comment asserted, without any supporting evidence, that "genetic resistance to antibiotics in these plants could be transferred by plasmids to microorganisms in the soil and elsewhere in the food chain."

FDA agrees that increasing the number and prevalence of antibiotic-resistant microbes may have serious human health implications if those microbes are themselves pathogens of humans or domesticated animals, or share the same microenvironment as such pathogens. FDA considers the relevant scientific question to be whether there would be a meaningful increase in antibiotic-resistant pathogenic microbes in the human environment due to transfer of the *kan*^{r} gene from plants to microbes. This issue was also the subject of considerable discussion at the April 1994 Food Advisory Committee meeting. As discussed in detail above, FDA has determined, based on the body of evidence presented by Calgene and based on the discussions of the Food Advisory Committee (Ref. 1), that the transfer of the *kan*^{r} gene from plants to microbes will not occur at a detectable frequency and overall will result in no significant increase in the numbers of antibiotic-resistant microbes. Regarding whether Calgene should be required to determine experimentally the rate of transfer, the agency notes that Calgene's calculations represent worst-case scenarios, and the agency believes it would not be useful to do experiments to attempt to measure that which is too small to measure.

Regarding the relevance of experiments on bacterial releases to the environment, FDA finds that information concerning the lack of an environmental effect from the release of microbes with and without antibiotic resistance genes is of limited direct relevance to the environmental effects of plants with antibiotic resistance genes. The agency did not rely on this information in reaching its determination that there will be no significant increase in the antibiotic-resistant microorganism population of the soil.

Finally the claim that the *kan*^{r} gene could be transferred from plants to bacteria by plasmids is without basis because there is no evidence that plasmids exist in plants.

2. Potential Transfer of the *kan*^{r} Gene to Other Crops and to Wild Relatives

Comments were also received on the potential transfer of the *kan*^{r} gene to other crops and wild relatives. These comments address environmental issues and do not bear on the safety of APH(3')II for its proposed food additive use and are therefore addressed in section VII. of this document.

E. Possible Effects of Consumption of Animal Feeds Containing APH(3')II on Animals and Their Gut Microflora

One comment argued that empirical evidence should be gathered to assess the potential effects of modified foods on animals and their gut microflora.

The agency is aware of no information that APH(3')II would affect animals or their gut microflora any differently than any other protein in the diet, nor did the

[7] Plasmids are self-replicating units of DNA commonly found in bacteria and are responsible for transfer of antibiotic resistance between bacteria.

comment provide such information. The comment may have been referring to the theoretical potential for APH(3')II in animal feed to affect efficacy of neomycin administered to animals, and the theoretical potential for the gut microflora to take up the *kan*^{r} gene and become resistant to neomycin. As discussed above, the likelihood of transfer of the *kan*^{r} gene to gut microflora of food animals is extremely remote. Also, as discussed above, FDA has evaluated the study presented by Calgene addressing the possibility of inactivation of neomycin by APH(3')II in animal feed and has concluded that the therapeutic efficacy of neomycin in animals would not be affected by consumption of feed containing transgenic cottonseed and rapeseed modified through the use of the *kan*^{r} gene.

F. Labeling of Foods Containing the Kan^r *Gene and APH(3')II*

One comment asserted that APH(3')II should be labeled as an ingredient. The comment further stated that, if FDA exempted APH(3')II from ingredient labeling requirements (based on its classification as a processing aid that is present at insignificant levels in a finished food and has no technical or functional effect in that food), FDA should require special labeling if the ingestion of food containing APH(3')II could compromise the clinical efficacy of orally administered kanamycin or neomycin.

FDA's authority over food labeling is based on section 403 of the act (21 U.S.C. 343). Section 403(i) of the act requires that, in the case of foods fabricated from two or more ingredients, a food product bear on the label the common or usual name of each ingredient, unless compliance with the requirement for labeling is impracticable or results in deception or unfair competition. FDA considers an "ingredient" to be a substance used to fabricate (i.e., manufacture or produce) a food. FDA does not consider those substances that are inherent components of food to be ingredients that must be disclosed in the food's label.

A genetic substance introduced into a plant by breeding becomes an inherent part of the plant as well as of all foods derived from the plant. Consistent with FDA's general approach on ingredient labeling, the agency has not treated as an ingredient a new constituent of a plant introduced by breeding, regardless of the method used to develop the new plant variety. The comment provides no basis for FDA to deviate from its current practice in the case of APH(3')II.[8] Accordingly, FDA has determined that neither the *kan*^{r} gene nor APH(3')II is an ingredient that, under section 403(i) of the act, must be individually identified in labels of foods containing them.

FDA has also determined that the presence of APH(3')II is not a material fact that must be disclosed in the labeling of foods that contain the enzyme. Under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)), a food is misbranded if its labeling is false or misleading. Under section 201(n) of the act (21 U.S.C. 321(n)), labeling is misleading if it fails to reveal all facts that are "* * * material with respect to consequences which may result from the use of the article * * *." As discussed at length above, FDA has determined that the ingestion of food containing APH(3')II will not compromise the clinical efficacy of orally administered kanamycin or neomycin. Because the consequences alleged in the comment—compromise of clinical efficacy—will not occur, the presence of APH(3')II is not a material fact requiring disclosure.

V. Conclusions

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of APH(3')II as a processing aid in the development of new varieties of tomato, oilseed rape, and cotton is safe, and that 21 CFR parts 173 and 573 should be amended as set forth below.

VI. Inspection of Documents

In accordance with §§ 171.1(h) and 571.1(h) (21 CFR 171.1(h) and 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h) and 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

Calgene's initial submission requesting an advisory opinion regarding whether the *kan*^{r} gene may be used in the production of genetically engineered tomato, cotton, and oilseed rape plants included an environmental assessment (EA). The agency received comments on this EA. As noted earlier, the request for advisory opinion was later converted to a food additive petition at Calgene's request at which time Calgene submitted an updated EA. At the time the notice of filing was published in the **Federal Register**, FDA announced that the petitioner's EA was being made available to the public at the Dockets Management Branch (address above) and expressly solicited comments on the EA. No additional comments were received in response to this request for comments. The comments received on the original EA are discussed below.

One comment asserted that the *kan*^{r} gene could spread from tomato, cotton, and oilseed rape plants to other crops and related weeds by pollen flow when the *kan*^{r} gene-containing crops are grown near nontransgenic crops, and in locations where the *kan*^{r}-gene containing crops have wild relatives. The comment noted that transfer of the *kan*^{r} gene would create a problem if it were to make wild and weedy relatives more difficult to control.

The comment also criticized the Calgene submission for not addressing whether it is "wise to contribute foreign genes to the gene pools of wild plants even where the plants do not become weeds or manifest other obviously harmful traits" and stated that Calgene's submission "too easily dismissed the problem of outcrossing from the engineered oilseed rape." The comment noted that oilseed rape has wild and weedy relatives with which it can breed, and that "it is not sufficient to rely on traditional commercial control practices to control gene flow," but that the rate of gene flow must be experimentally determined and then "controlled by procedures that are demonstrated, not assumed, to work."

The agency has considered the potential for adverse environmental effects from the commercial use of cotton, tomato, and oilseed rape plants modified to contain the *kan*^{r} gene. The agency notes that it is possible for cotton and tomato plants to transfer the *kan*^{r} gene to neighboring plants of the same species via cross-pollination, although commercially grown cotton and tomatoes are primarily self-pollinating. Oilseed rape plants are also capable of pollinating sexually compatible wild relatives, although not all crosses with wild relatives prove fertile. Importantly, however, introduction of the *kan*^{r} gene will not

[8] Furthermore, APH(3')II satisfies the definition of "processing aid" in § 101.100(a)(3)(ii)(c) (21 CFR 101.100(a)(3)(ii)(c)) and will be regulated as such by this final rule. As the comment acknowledges, FDA's labeling regulations exempt processing aids like APH(3')II from the labeling requirements of section 403(i)(2) of the act. Thus, even if APH(3')II were properly considered an ingredient, its presence in a food would not be required to be disclosed in the food's labeling.

confer a competit've advantage upon a plant receiving it That is, the gene will not enhance the plant's capacity to compete with other plants for available resources. In particular, there will be no selective pressure on plants containing the *kan*^{r} gene because kanamycin will not be present in the environment in sufficient concentrations to create such pressure. First, there are no specific therapeutic uses of kanamycin that would result in its widespread application to agricultural crops. Also, kanamycin does not accumulate in the environment from production by soil microbes or by land application of animal wastes (Ref. 36). Accordingly, FDA has concluded that transfer of the *kan*^{r} gene to other crops or related weeds will have no significant adverse environmental effects.

With regard to the comment about outcrossing from engineered oilseed rape, the comment provided no information to show that the transfer of the *kan*^{r} gene to wild or weedy relatives of oilseed rape will be any more frequent or have any greater significance than the transfer of other genes from cultivated oilseed rape. FDA is aware of no human health or environmental concern associated with such transfer. Therefore, the agency does not agree that the cultivation of *kan*^{r}-containing oilseed rape should be subject to control practices any different from those used traditionally.

The agency has carefully considered the potential environmental effects of this action, including those described in the comments discussed in this document. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 22, 1994, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Transcript of meeting of the Food Advisory Committee, FDA, Herndon, VA, April 6 through 8, 1994.

2. Hoskins, L.C., "Host and Microbial DNA in the Gut Lumen," The Journal of Infectious Diseases, 137:694–698, 1978.

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7. Jorgensen, R.A. et al., "A Restriction Enzyme Cleavage Map of Tn^5 and Location of a Region Encoding Neomycin Resistance," Molecular and General Genetics, 177:65–72, 1979.

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11. Prescott, J.F., and J.D. Baggot, "Aminoglycosides and Aminocyclitols," in Antimicrobial Therapy in Veterinary Medicine, Blackwell Scientific Publications, Boston, MA, pp. 121–152, 1988.

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14. Nap, J.P et al., "Biosafety of Kanamycin-resistant Transgenic Plants," Transgenic Research, 1:239–249, 1992.

15. Taylor, S.L. et al.,"Food Allergens: Structure and Immunologic Properties," Annals of Allergy, 59:93–99, 1987.

16. Darnel, J. et al., "Molecular Cell Biology," 2d ed., p. 116, Scientific American Books, Inc.

17. Pariza, M.W. et al., "Determining the Safety of Enzymes Used in Food Processing," Journal of Food Protection, 46:453–468, 1988.

18. Memorandum from Z. Olempska-Beer, FDA, to N. Beru, FDA, August 10, 1993.

19. Memorandum from Z. Olempska-Beer, FDA, to J. Maryanski, FDA, July 14, 1992.

20. Memorandum from C.B. Johnson, FDA, to V. Zenger, FDA, September 7, 1993.

21. Memorandum from C.B. Johnson, FDA, to J. Maryanski, FDA, July 14, 1992.

22. Fuchs, R.L. et al., "Safety Assessment of the Neomycin Phosphotransferase II (NPTII) Protein," Biotechnology, 11:1543–1547, 1993.

23. USDA Agricultural Handbook No. 8, Table I, Item 1401.

24. Memorandum from Z. Olempska-Beer, FDA, to N. Beru, FDA, August 9, 1993.

25. Orten, J.M. and O.W. Neuhaus, Human Biochemistry, 10th ed., pp. 537–538, C.V. Mosby Co., St. Louis, MO, 1982.

26. Memorandum from A.T. Sheldon, FDA, to J. Maryanski, FDA, March 30, 1993.

27. Memorandum from S.A. Giduck, FDA, to V. Zenger, FDA, July 21, 1992.

28. Memorandum from J.D. McCurdy, FDA, to V. Zenger, FDA, October 13, 1993.

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36. Memorandum from J. Glover-Glew, FDA, to N. Beru, FDA, December 15, 1993.

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List of Subjects

21 CFR Part 173

Food additives.

21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 173 and 573 are amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. New § 173.170 is added to subpart B to read as follows:

§ 173.170 Aminoglycoside 3'-phosphotransferase II.

The food additive aminoglycoside 3'-phosphotransferase II may be safely used in the development of genetically modified cotton, oilseed rape, and tomatoes in accordance with the following prescribed conditions:

(a) The food additive is the enzyme aminoglycoside 3'-phosphotransferase II (CAS Reg. No. 58943–39–8) which catalyzes the phosphorylation of certain aminoglycoside antibiotics, including kanamycin, neomycin, and gentamicin.

(b) Aminoglycoside 3'-phosphotransferase II is encoded by the *kan*^{r} gene originally isolated from transposon Tn^{5} of the bacterium *Escherichia coli.*

(c) The level of the additive does not exceed the amount reasonably required for selection of plant cells carrying the *kan*^{r} gene along with the genetic material of interest.

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

3. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

4. New § 573.130 is added to subpart B to read as follows:

§ 573.130 Aminoglycoside 3'-phosphotransferase II.

The food additive aminoglycoside 3'-phosphotransferase II may be safely used in the development of genetically modified cotton, oilseed rape, and tomatoes in accordance with the following prescribed conditions:

(a) The food additive is the enzyme aminoglycoside 3'-phosphotransferase II (CAS Reg. No. 58943–39–8) which catalyzes the phosphorylation of certain aminoglycoside antibiotics, including kanamycin, neomycin, and gentamicin.

(b) Aminoglycoside 3'-phosphotransferase II is encoded by the *kan*^{r} gene originally isolated from transposon Tn5 of the bacterium *Escherichia coli.*

(c) The level of the additive does not exceed the amount reasonably required for selection of plant cells carrying the *kan*^{r} gene along with the genetic material of interest.

Dated: May 17, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 94–12492 Filed 5–18–94; 12:39 pm]

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Monday
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Part III

Department of Energy

10 CFR Part 765

Reimbursement for Costs of Remedial Action at Active Uranium and Thorium Processing Sites; Final Rule and Notice

DEPARTMENT OF ENERGY

10 CFR Part 765

[1901–AA53]

Reimbursement for Costs of Remedial Action at Active Uranium and Thorium Processing Sites

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy, Office of Environmental Management, is promulgating this final rule to establish requirements governing reimbursement for certain costs of decontamination, decommissioning, reclamation, and other remedial action incurred by licensees at active uranium or thorium processing sites to remediate byproduct material generated as an incident of sales to the United States Government. The Energy Policy Act of 1992 requires the Department of Energy to implement these requirements of Title X and establish procedures for eligible licensees to submit claims for reimbursements.

EFFECTIVE DATE: June 22, 1994.

ADDRESSES: The official record for this rulemaking activity is available for public review in the Department of Energy Freedom of Information Reading Room, 1000 Independence Avenue, SW., Washington, DC, from 9:30 a.m. to 4:30 p.m., Monday through Friday. The Department's standardized claims format guide and annual report will be available upon written request to the Uranium Mill Tailings Remedial Action Project Office, U.S. Department of Energy, 2155 Louisiana NE., suite 10000, Albuquerque, NM 87110.

FOR FURTHER INFORMATION CONTACT: David Mathes, Office of Environmental Management (EM–45), U.S. Department of Energy, (301) 903–7223, or Steven Hamp, Uranium Mill Tailings Remedial Action Project Office, U.S. Department of Energy, (505) 845–4628.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

A. Statutory Authority

Title X of the Energy Policy Act of 1992 (Sections 1001–1004 of Public Law 102–486, 42 U.S.C. 2296a *et seq.* (hereinafter "the Act")), enacted on October 24, 1992, requires the Department of Energy (hereinafter the "Department") to reimburse eligible uranium and thorium licensees for certain costs of decontamination, decommissioning, reclamation, and other remedial action at active uranium or thorium processing sites, which also include vicinity properties. Consistent with section 1002 of the Act (42 U.S.C. 2296a–1) the Department is promulgating this final rule to implement the requirements of Title X and to establish procedures for eligible applicants to submit claims for reimbursement.

Title X provides that, with certain exceptions, remedial action costs at active uranium or thorium processing sites shall be borne by persons licensed under section 62 or 81 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2092, 2111) (hereinafter the "Atomic Energy Act"). Section 1001(b)(1)(B) of the Act (42 U.S.C. 2296a(b)(1)(B)) requires the Department to reimburse eligible licensees of an active processing site a portion of the costs determined by the Department to be attributable to byproduct material generated as an incident of sales to the United States and either (a) Incurred by such licensee not later than December 31, 2002; or (b) placed in escrow not later than December 31, 2002, and incurred by the licensee in accordance with a plan for subsequent decontamination, decommissioning, reclamation, and other remedial action approved by the Department.

In order to be reimbursable, such costs must be for work which is necessary to comply with applicable requirements of the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7901 *et seq.*) (hereinafter "UMTRCA") or, where appropriate, with requirements established by a state pursuant to a discontinuance agreement under section 274 of the Atomic Energy Act (42 U.S.C. 2021), hereinafter "Agreement State". In addition, claims for reimbursement of costs of remedial action must be supported by reasonable documentation as determined by the Department.

Section 1001(b)(2) of the Act (42 U.S.C. 2296a(b)(2)) limits the amount of reimbursement paid to any one licensee of an active uranium mill tailings site to an amount not to exceed $5.50 multiplied by the dry short tons of byproduct material located at the site on October 24, 1992, and generated as an incident of sales to the United States. Total reimbursement, in the aggregate, for work performed at active uranium sites shall not exceed $270 million. Total reimbursement for work performed at the active thorium site shall not exceed $40 million, and is limited to costs incurred for offsite disposal. Under sections 1001(b)(2)(D) and 1003(a) of the Act (42 U.S.C. 2296a(b)(2)(D) and 2296a–2(a)), the $5.50 per dry short ton limit on reimbursement to individual uranium site licensees and aggregate ceilings shall be subject to annual adjustment for inflation based upon an inflation index chosen by the Department.

B. Background

1. Overview of Uranium Processing Activity Licensed Under the Atomic Energy Act

The U.S. Army's Manhattan Engineer District, from 1942 to 1946, and later the Atomic Energy Commission (hereinafter "AEC"), from 1947 through 1970, entered into several contracts for the purchase of uranium concentrate to support the Nation's defense programs. Initially, four mills provided uranium for the Army, primarily through reprocessing radium and vanadium mill tailings. Eventually a total of 34 commercially operated mills produced uranium concentrate for sale to the United States Government.

These contracts were for the purchase of an agreed-upon quantity of uranium concentrate. Contract specifications addressed physical characteristics, grade, and impurities but did not include provisions for mill decommissioning, long-term management of the milling-process wastes, known as tailings, or stabilization of tailings piles. When these contracts were executed, the potential hazards of tailings were not fully recognized. Over the ensuing decades, however, potential radiological and chemical hazards associated with uranium and thorium mill tailings were identified and standards and requirements were developed for the control and management of tailings.

Between 1975 and 1979, the Department and the Energy Research and Development Administration, successor agencies to the AEC, completed studies of uranium mill sites that had produced uranium concentrate for the AEC, had subsequently ceased operations, and were considered inactive. These studies determined that uranium mill tailings located at these inactive uranium milling sites posed potentially significant health hazards to the public and that a program should be developed to ensure proper stabilization or disposal of these tailings to prevent or minimize radon diffusion into the environment and other related hazards.

2. Overview of Uranium Mill Tailings Radiation Control Act

As a result of these studies, in November 1978, Congress enacted UMTRCA, which authorizes the Department to undertake remedial action at "inactive" uranium milling sites and at vicinity properties contaminated with residual radioactive material [1] generated at a site. Inactive uranium milling sites are those which were no longer licensed under the Atomic Energy Act on January 1, 1978, and where all or substantially all of the uranium concentrate was produced for the Federal Government. The Department conducts remedial action in coordination with affected States and Indian tribes under cooperative agreements at 24 inactive sites.

In addition, UMTRCA established a program authorizing the United States Nuclear Regulatory Commission (hereinafter "NRC") to regulate mill tailings generated during processing operations at "active" processing sites (*i.e.*, sites with active licenses under the Atomic Energy Act on or after January 1, 1978) to ensure sound management of tailings throughout the production, reclamation and disposal phases.

3. Legislative Background

UMTRCA did not provide for payment of costs of remedial action incurred at active uranium processing sites which were contaminated with uranium mill tailings generated under Federal contract. Two reports prepared subsequently for Congress, by the Department in January 1979 [2] and by the General Accounting Office in February 1979,[3] concluded that Federal assistance should be provided to licensees at these sites to address the cost of remediating mill tailings that were generated under contracts with the United States Government.

Congress directed the Department, through section 213 of Public Law 96–540, to develop a plan for establishing a cooperative program to provide Federal assistance in the stabilization and management of uranium mill tailings generated as an incident of sales to the United States Government which are commingled with other tailings. The Department was directed to identify, among other things, the amount of tailings generated under Federal contract at each active site. This determination was to be used to calculate the percentage of such tailings in relation to total tailings at each site, and the corresponding share of Federal assistance appropriate to meet the costs of stabilizing and managing tailings as required by Federal law.

Title X establishes the authority and framework for providing this Federal assistance. The Department is required to issue regulations governing reimbursement to licensees at active uranium and thorium processing sites for certain costs of remedial action. This final rule establishes the requirements and procedures under which the Department will implement this reimbursement program.

II. Response to Public Comments on the Proposed Rule

The Department's proposed rule was published on August 9, 1993 (58 FR 42450). A public hearing was held on September 14, 1993 in Denver, Colorado. A total of 16 written comments were received, of which four identical comments were also presented orally at the public hearing. Most of the comments concerned eligibility for reimbursement, reimbursable costs, determination of the Federal reimbursement ratio, definition of byproduct material, and claim documentation requirements. These and all other comments to the proposed rule are discussed below.

A. Eligibility for Reimbursement

Subject to certain specific limitations set forth in section 1001(b) of the Act (42 U.S.C. 2296(a)(b)), Title X requires the Department to reimburse licensees of active uranium or thorium processing sites for that portion of remedial action costs that may be attributed to byproduct material generated as an incident of sales to the United States. Parties eligible for reimbursement must be, or have been, licensed under section 62 or 81 of the Atomic Energy Act, and must have incurred costs of "decontamination, decommissioning, reclamation, or other remedial action" at an "active uranium or thorium processing site," as those terms are defined by Title X, sections 1004(3) and 1004(1), respectively (42 U.S.C. 2296a–3(3) and 2296a–3(1)). A number of comments were received requesting clarification or revision of the proposed rule's requirements concerning eligibility for reimbursement.

One commenter requested that the proposed rule's definition of "licensee" be changed to specifically include entities licensed by an Agreement State. Sections 1001(a) and (b) of the Act (42 U.S.C. 2296a(a) and (b)) require that the Department reimburse "persons licensed under section 62 or 81 of the

[1] The term "residual radioactive material" is defined by Section 101(7) of UMTRCA (42 U.S.C. 7911(7)) to mean: "(A) Waste (which the Secretary determines to be radioactive) in the form of tailings resulting from the processing of ores for the extraction of uranium and other valuable constituents of the ores; and (B) other waste (which the Secretary determines to be radioactive) at a processing site which relate to such processing, including any residual stock or unprocessed ores or low-grade materials."

[2] "Answers to Questions on Commingled Tailings at Currently Operating Uranium Ore Processing Mills That Produced Uranium Under Atomic Energy Commission Contracts" (Department of Energy, January 29, 1979).

[3] "Cleaning Up Commingled Uranium Mill Tailings: Is Federal Assistance Necessary" (General Accounting Office, EMD–79–29, U.S. Department of Commerce, February 5, 1979).

Atomic Energy Act of 1954." Both section 62 and section 81 confer licensing authority to AEC and its successor agency, the NRC.

However, NRC and a state may enter into an agreement pursuant to section 274 of the Atomic Energy Act which provides for discontinuance of the regulatory authority of the NRC under Chapters 6, 7, and 8, and section 161 of the Atomic Energy Act when the NRC finds, upon certification by the Governor, that the state's program is in all respects compatible with the NRC's program for the regulation of byproduct and source material. The discontinuance of NRC authority is coupled with the Agreement State's issuance of licenses pursuant to a counterpart to section 62 or 81 of the Atomic Energy Act, under state law.

If an Agreement State has received authority pursuant to a discontinuance agreement to issue licenses under either section 62 or section 81 of the Atomic Energy Act, recipients of an Agreement State-issued license, that was in effect or pending on January 1, 1978, are eligible to apply for reimbursement under Title X. In addition, some active site licensees have been subject to remedial action requirements established both by NRC and an Agreement State. Accordingly, the definition of "licensee" in the proposed rule has been revised to clarify that a person licensed under the authority of either section 62 or 81 of the Atomic Energy Act, by NRC, or under state law by an Agreement State, or both, is eligible to apply for reimbursement of costs of remedial action. This approach is consistent with, and reflected by, the definition of "active uranium or thorium processing site" in section 1004(1) of the Act (42 U.S.C. 2296a–3(1)), which specifies that the license for the production of uranium or thorium derived from ore may be issued by NRC, AEC, or by an Agreement State.

Several comments were also received concerning the proposed eligibility requirement that a licensee also be a "site owner" of an active processing site. These commenters pointed out that land ownership was not intended by Congress to be a requirement for reimbursement. One commenter indicated that ownership of the property on which its processing site is located is divided between private, Federal, and state parties. Other commenters were concerned that the intent of Title X would be contravened if land ownership was a condition of eligibility for reimbursement. These commenters suggested that land ownership could also be difficult to define and determine.

While section 1002 of the Act (42 U.S.C. 2296a–1) appears to contemplate that applications for reimbursements will be made by "a site owner," section 1001(b)(2)(A) of the Act (42 U.S.C. 2296a(b)(2)(A)) specifically refers to reimbursements paid "to any licensee," and the remainder of Title X is also drafted in terms of payments to licensees. The term site owner, as used in section 1002 (42 U.S.C. 2296a–1), is not defined nor is there any legislative history that sheds light on the single reference to "site owner" in section 1002. Consistent with apparent Congressional intent, the Department has interpreted the term "site owner" to include any person that currently holds, or held in the past, any interest in land, including but not limited to a fee simple absolute, surface or subsurface ownership of mining claims, easements, or a right of access for the purposes of remediation, or any other legal or equitable interest. The Department has concluded that this definition will encompass all eligible current and former licensees. To avoid unnecessary confusion, the term "site owner" is not used in the rule and the term "licensee" is used instead.

B. Costs Eligible for Reimbursement

Several commenters proposed changes to, or requested clarification of, the language in § 765.11(a) of the proposed rule concerning reimbursable costs and the definition of "costs of remedial action." The proposed rule defined such costs as those costs incurred by a licensee that were necessary to perform "decontamination, decommissioning, reclamation, and other remedial action." The phrase "decontamination, decommissioning, reclamation, and other remedial action" is defined by section 1004(3) of the Act (42 U.S.C. 2296a–3(3)), as well as the proposed rule, as work "necessary to comply with all applicable requirements of" UMTRCA or, where appropriate, with requirements established by an Agreement State.

Several commenters asked that the definition of "costs of remedial action" specifically include a list of cost categories that are eligible for reimbursement. Furthermore, some commenters suggested that this list should specifically include the cost of capital, cost of equipment, and interest that might have been earned over the period between the expenditure and reimbursement; administrative costs; and costs in implementing other environmental program requirements.

In response to these comments, the Department has revised the definition of "costs of remedial action" to include those activities specified in the Joint Explanatory Statement of the Committee of Conference that accompanied the enactment of Title X which states:

> Funds made available under this program are intended to be provided for all costs that result from the disposition of by-product [sic] material at active processing sites (subject to the limitations of sec. 1001(b)), including groundwater remediation, treatment of contaminated soil, disposal of process wastes, removal actions, air pollution studies, mill and equipment decommissioning, site monitoring, administrative expenses, and additional expenditures required by related standards and regulations." (H.R. CONF. REP. NO. 102–1018, 102d Cong., 2d Sess. 392 (1992))

Rather than further attempt to enumerate more precise activities and circumstances for which costs are reimbursable, the Department has determined that this issue should be resolved on a case-by-case basis, consistent with the statutory requirements. Section 1004(3) of the Act (42 U.S.C. 2296a–3(3)) limits reimbursement to costs for "work performed . . . which is necessary to comply" with UMTRCA or, where appropriate, with applicable Agreement State requirements. Therefore, whether work for which reimbursement is sought is necessary to comply with UMTRCA or, where appropriate, with applicable Agreement State requirements as required by section 1004(3) of the Act (42 U.S.C. 2296a–3(3)), will depend on specific circumstances that may vary from one site to the next.

However, in the absence of specific statutory authority, the Department has determined that the carrying cost of past expenditures or other costs of capital or lost interest are not eligible for reimbursement. Costs incurred for activities required by other Federal and state regulatory authorities may only be considered reimbursable if the activity falls within the final rule's definition of "decontamination, decommissioning, reclamation, and other remedial action." For example, the United States Environmental Protection Agency or a state regulatory authority may require a licensee to obtain a storm water discharge permit pursuant to the Clean Water Act before the licensee is able to conduct a remedial action. Therefore, a licensee may be able to demonstrate that the cost in obtaining and maintaining the a discharge permit is necessary to comply with UMTRCA or, where appropriate, with Agreement State requirements.

Administrative costs and other costs associated with cleanup or restoration of the site may be eligible for reimbursement provided that a licensee

can demonstrate that the costs were necessary to comply with the requirements of UMTRCA or, where appropriate, with applicable requirements of an Agreement State.

Several commenters construed the proposed rule to limit costs of remedial action to activities required by an approved site reclamation plan. These commenters requested that the rule be clarified to provide for reimbursement of other activities required by other written authorization from NRC or an Agreement State.

The final rule clarifies that costs for activities required by NRC or an Agreement State and established by a license condition or other authorization or directive may be eligible for reimbursement. The phrase "or other written authorization" is used throughout the final rule to specify that the activity may be authorized by the applicable regulatory authority by some mechanism other than an approved reclamation plan.

Several commenters requested that the final rule specify that costs incurred prior to the enactment of UMTRCA are reimbursable. This request is consistent with section 1001(b)(1) of the Act (42 U.S.C. 2296a(b)(1)), which provides that the Secretary shall reimburse a licensee for costs of decontamination, decommissioning, reclamation, and other remedial action which are attributable to byproduct material generated as an incident of sales to the United States and incurred by the licensee not later than December 31, 2002. Furthermore, section 1004(3) of the Act (42 U.S.C. 2296a–3(3)) specifies that the term "decontamination, decommissioning, reclamation, and other remedial action" means work performed that is necessary to comply with UMTRCA or, where appropriate, requirements established by an Agreement State.

Therefore, the final rule states that pre-UMTRCA costs may be eligible for reimbursement if the licensee can demonstrate and obtain the Department's approval that the work was necessary to comply with UMTRCA. A licensee can make this demonstration by providing a written authorization from the NRC or an Agreement State which indicates that the work performed by the licensee prior to the enactment of UMTRCA was necessary to comply with UMTRCA or, where appropriate, with applicable Agreement State requirements.

Some commenters objected to § 765.11(a) of the proposed rule, concerning the requirement that reimbursable costs must be for activities "contributing to final closure." These commenters were concerned that the applicable regulatory authority may revise an approved reclamation plan, license condition, or other directive for the remediation of the site. Under the proposed rule, a licensee's previously incurred costs of remedial action would not be reimbursable. The Department acknowledges this concern and has revised the final rule by deleting this requirement.

In addition, commenters objected to § 765.20 of the proposed rule which required licensees to certify that remedial action work was completed as required by a reclamation plan or other written authorization. These commenters were concerned that licensees might not be reimbursed prior to completion of remedial actions for individual tasks, as specified in an approved reclamation plan or other written authorization, upon the licensees completion of these tasks. The Department agrees with these commenters and notes that it is the Department's intent to reimburse these costs upon completion of the individual tasks instead of the entire remediation.

Finally, one commenter suggested that § 765.2(d) of the proposed rule be modified to clarify that expenses incurred as a result of an NRC directive, an Agreement State directive, or both, are eligible for reimbursement. A mill may have been regulated by both the NRC and an Agreement State during the mill's history, and may have therefore incurred costs for activities required by directives from both regulatory authorities. This commenter urged that references to "NRC or Agreement State" be revised to read "NRC and/or an Agreement State."

The Department has retained the proposed language but wishes to clarify that use of the phrase "NRC or an Agreement State" refers to NRC, an Agreement State, or both.

C. Determining the Federal Reimbursement Ratio

The proposed rule provided that the Department would establish a "Federal reimbursement ratio" to determine the portion of costs of remedial action attributable to byproduct material generated as an incident of sales to the United States. Under the proposed rule, the Federal reimbursement ratio would be the ratio of Federal-related dry short tons of byproduct material to total dry short tons of byproduct material present at each site on the date of enactment of Title X.

Some commenters suggested that the Department should allow licensees to use a method other than the proposed rule's tonnage or quantity-based approach to establish a site's Federal reimbursement ratio. These commenters argued that at some sites the tonnage-based Federal reimbursement ratio may not accurately reflect the true costs of remediation attributable to byproduct material generated as an incident of sales to the United States. These commenters also suggested that the rule allow greater flexibility in the methods available to determine the Federal reimbursement ratio. In particular, these commenters requested that the rule allow such ratio to be based on the acreage covered by Federal-related dry short tons of byproduct material compared to the total acreage covered by all dry short tons of byproduct material at the site.

Title X limits reimbursement to costs "attributable to" byproduct material generated as an incident of sales to the United States, but does not require a specific method for determining how to attribute costs to byproduct material generated as an incident of sales to the United States. Section 1001(b)(2)(A) of the Act (42 U.S.C. 2296a(b)(2)(A)) establishes a $5.50 per dry short ton of byproduct material limit on reimbursement. This indicates that the tonnage approach is an appropriate method for determining the Federal portion of remedial action costs. However, the tonnage approach may not, in some cases, most accurately reflect the portion of costs attributable to byproduct material generated as an incident of sales to the United States. As the Department recognized in the "Commingled Uranium Tailings Study, Volume II: Technical Report," (Department of Energy, June 30, 1982) different approaches for allocating costs attributable to byproduct material generated as an incident of sales to the United States may be appropriate, depending on the unique characteristics at each site.

Accordingly, the final rule has been revised to allow a licensee to demonstrate that an alternative method for determining the Federal reimbursement ratio, other than the tonnage approach, should be used. In order to make this demonstration, the final rule requires the licensee to demonstrate to the satisfaction of the Department that such alternative method is more accurate than the tonnage-based approach in delineating between costs of remedial action attributable to byproduct material generated as an incident of sales to the United States and costs attributable to other byproduct material at the site. Any licensee requesting that the Department consider an alternative approach for establishing a site's Federal

reimbursement ratio, must submit the request in writing, together with any information the licensee wants the Department to consider in support of the request. The Department reserves the right to approve or reject the alternative method, based on the Department's determination of whether such method may provide an effective, accurate, and verifiable means of attributing costs of remedial action for byproduct material generated as an incident of sales to the United States. Regardless of the methodology used to establish the Federal reimbursement ratio, the statutory ceiling on reimbursements to licensees will not change.

D. Definition of Byproduct Material and Dry Short Tons of Byproduct Material; and Determination of Reimbursement Ceiling at Each Active Uranium Processing Site

One commenter disagreed with the proposed rule's definition of "dry short tons of byproduct material." This commenter requested that the definition be expanded to include other wastes as well as tailings. For the reasons stated below, the Department has not adopted this approach.

Section 1001(b)(2)(A) of the Act (42 U.S.C. 2296(a)(b)(2)(A)) requires that the ceiling for uranium mill tailings sites shall not exceed an amount equal to $5.50 multiplied by the dry short tons of byproduct material onsite on the date of Title X's enactment and generated as an incident of sales to the United States. Although Title X incorporates by reference the Atomic Energy Act's definition of "byproduct material,"[4] the phrase "dry short ton of byproduct material" is not defined in either Act. While the definition of "byproduct material" could be read to suggest that the term includes wastes other than tailings, section 1001(b)(2)(A) of the Act (42 U.S.C. 2296a(b)(2)(A)) appears to use the phrase "uranium mill tailings" interchangeably in the same sentence with the phrase "byproduct material." The apparent interchangeable use of these terms is further reflected by the fact that House Bill 776[5], which ultimately was enacted, established a reimbursement limit of $5.50 per "dry short tons of byproduct *material*," (emphasis added) while the section-by-section analysis of the House Energy and Commerce Report[6] accompanying the bill described the limit as "$5.50 per dry ton for uranium *tailings*" (emphasis added).

Consequently, for the purposes of this rule's maximum reimbursement ceiling determination for active uranium processing site licensees and Federal reimbursement ratio for uranium and thorium licensees, the Department is defining the phrase "dry short ton of byproduct material" in the final rule to mean "the quantity of tailings generated from the extraction and processing of 2,000 pounds of uranium or thorium ore-bearing rock."

One commenter requested that the proposed definition of "tailings" be revised to conform to the definition established by section 101(8) of UMTRCA (42 U.S.C. 7911(8)). The Department agrees with this comment and has revised the definition accordingly.

The following table establishes the Department's determination as to the quantity of Federal-related dry short tons of byproduct material and total dry short tons of byproduct material present at each active uranium or thorium processing site as of October 24, 1992. The data from which these quantities are derived were obtained from the reports entitled "Commingled Uranium Mill Tailings Study, Volume II: Technical Report," (DOE, June 30, 1982) and "Integrated Data Base for 1992: U.S. Spent Fuel and Radioactive Waste Inventories, Projections, and Characteristics" (DOE/RW 0006, Rev. 8). In some cases, this data was updated based on the Department's review of quantity information provided by some licensees in response to the proposed rule. These quantity reports are available in the Department's Freedom of Information Reading Room indicated in the ADDRESSES section of this preamble. These quantities shall be the basis for the Department's determination of the Federal reimbursement ratio applicable to each active processing site, unless a licensee requests and the Department agrees to use an alternative method for computing the ratio. These quantities will also be the basis for the Department's determination of the individual maximum reimbursement ceiling applicable to each active uranium processing site.

Although Title X provides that the per dry short ton limit on reimbursement for each eligible uranium licensee shall not exceed an amount equal to $5.50, as adjusted for inflation, the Department is authorized to establish a lower per dry short ton limit if necessary. Based on the total quantity of 56.231 million Federal-related dry short tons of byproduct material, the Department is establishing an initial per dry short ton limit of $4.80. This is necessary because the aggregate $270 million statutory ceiling will not support the maximum allowable reimbursement of $5.50 per dry short ton, as established by the Act, if remedial action costs at all of the eligible uranium processing sites reach or approach this per dry short ton limit (*i.e.*, $270 million divided by 56.231 million Federal-related dry short tons of byproduct material equals $4.80 per dry short ton). The Department will adjust the preliminary limit on reimbursement accordingly when the $270 million statutory ceiling is adjusted annually for inflation or if other circumstances, as determined by the Department, enable the adjustment of the preliminary limit.

DRY SHORT TONS OF BYPRODUCT MATERIAL

[Millions]

Licensee/active uranium site	Federal related	Total	Federal reimbursement ratio
American Nuclear Corp., Gas Hills Mill Site, (Gas Hills, WY)	2.191	6.0	0.365
Atlantic Richfield Company, Blue Water Mill Site, (Grants, NM)	8.837	23.9	.370
Atlas Corp., Moab Mill Site, (Moab, UT)	5.946	10.6	.561
Cotter Corp., Canon City Mill Site, (Canon City, CO)	.315	2.2	.143
Dawn Mining Company, Ford Mill Site, (Ford, WA)	1.171	3.1	.378
Homestake Mining Company, Grants, Mill Site, (Grants, NM)	11.411	22.3	.512
Pathfinder Mines Corp., Lucky McMine, (Riverton, WY)	2.842	11.7	.243

[4] Section 1004(2) of the Act (42 U.S.C. 2296a-3(2)) provides that the term "byproduct material" has the meaning given that term in section 11e.(2) of the Atomic Energy Act, which defines "byproduct material" as "the tailings or wastes produced from the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content."

[5] Section 1001(b)(2)(A) of H.R. 776, 102d Cong., 2d Sess. (1992).

[6] See H.REP. NO. 474, 102 Cong., 2d Sess. pt 1, at 205 (1992), *reprinted* in 1992 U.S.C.C.A.N. 2028.

DRY SHORT TONS OF BYPRODUCT MATERIAL—Continued

[Millions]

Licensee/active uranium site	Federal related	Total	Federal reimbursement ratio
Petrotomics Company, Shirley Basin Mill Site, (Shirley Basin, WY)	.725	6.3	.115
Quivira Mining Company, Ambrosia Lake Mill Site, (Grants, NM)	10.017	33.2	.302
Tennessee Valley Authority, Edgemont Mill Site, (Edgemont, SD)	1.625	2.0	.813
UMETCO Mineral Corp., Uravan Mill Site, (Nucla, CO)	5.701	10.5	.543
Union Carbide Corp., East Gas Hills Mill Site, (Gas Hills Station, WY)	2.103	8.0	.263
Western Nuclear, Inc., Split Rock Mill Site, (Jeffrey City, WY)	3.347	7.7	.435
Licensee/Active Thorium Site.			
Kerr-McGee Chemical, Corp., West Chicago, Thorium Mill Site, (West Chicago, IL)	0.032	.058	.552

E. Documentation Requirements

Section 765.20 of the proposed rule required that each claim for reimbursement of costs of remedial action be supported by adequate documentation. All costs for which reimbursement was sought and all supporting documentation were to be organized and cross-referenced to specific requirements or activities in an approved reclamation plan. Further, the proposed rule expressed a preference for documentation that was prepared contemporaneously to the time the costs were incurred.

A number of commenters questioned the use of the word "adequate" to describe the documentation necessary to support a claim for reimbursement. Section 1002 of the Act (42 U.S.C. 2296a–1)) requires a licensee to submit a claim together with "reasonable" documentation. In the final rule, the word "adequate" has been replaced with "reasonable" in § 765.20(a) to make the language of the rule consistent with that of Title X.

The proposed rule also generated several comments concerning the amount and type of documentation necessary. Many commenters contended that the documentation requirements were unduly burdensome. Several commenters recommended that the Department consider accepting a summary of the available documentation, while reserving the right to audit the actual documentation at the licensee's facility.

As a result of these comments, the Department has modified the documentation requirements in the final rule to specifically permit the submission of claims that summarize the supporting documentation, without requiring the submission of all supporting documentation with the claim itself. Under the final rule, licensees may submit a claim which outlines all costs of remedial action for which reimbursement is sought and summarizes the documentation available to support the claim. The Department may audit or may require the licensee to audit, on a case-by-case basis, any documents used in support of a claim. Under the final rule, licensees are still required to organize and cross-reference summary documentation supporting a claim to the activity or requirement established in the reclamation plan, or other written authorization for both pre- and post-UMTRCA costs of remedial action, in order to facilitate such an audit. These documents also must be retained by each licensee until 4 years after final payment of a claim is made by the Department, access to which must be made available to the Department upon request.

In addition, many commenters indicated that contemporaneous documentation might not be available to support claims. Various reasons, including the passage of time since costs were incurred, were provided to support the request that non-contemporaneous documentation be permitted to support the claim for reimbursement.

The proposed rule did not prohibit the use of non-contemporaneous documentation. Instead it established a preference, but not a requirement, for contemporaneous documentation. The final rule has been clarified to indicate that documentation prepared contemporaneous to the time the costs were incurred should be used where available. To support a claim for reimbursement, the most appropriate documentation, but not the only acceptable documentation, is documentation that was prepared contemporaneous to the time the cost was incurred. If contemporaneous documentation is not available, § 765.20(d)(2) provides that non-contemporaneous documentation may be submitted, provided that the documentation is the only means available to document the costs for which reimbursement is sought. This approach reflects the Department's understanding that Title X establishes a test of reasonableness regarding the level of documentation necessary to support a claim for reimbursement. The level of documentation that reasonably can be expected will depend on the specific circumstances involved in each claim, including the time that has elapsed since the costs were incurred and the activity for which costs were incurred. The Department intends to evaluate each claim on a case-by-case basis using this standard of reasonableness.

Some commenters requested that § 765.20(e) of the proposed rule be revised to exclude the requirement that the licensee certify that a quality assurance program was implemented. The Department has determined that this certification is not required by the Act, but rather is a responsibility of NRC or an Agreement State. Therefore, this requirement has been deleted from the final rule.

Finally, one commenter encouraged the Department to provide a standardized claims format guide so that guidance for preparing claims will be available to licensees when the rule is finalized. The Department is preparing guidance to aid licensees in claim submission procedures. This guide will be distributed to eligible licensees shortly after publication of the final rule. In addition, the guide will be made available to other interested parties upon written request to the Uranium Mill Tailings Remedial Action Project Office, U.S. Department of Energy, 2155 Louisiana NE., suite 10000, Albuquerque, NM 87110, or by visiting the Department of Energy's Freedom of Information Reading Room, 1000 Independence Avenue SW., Washington, DC, from 9:30 a.m. to 4:30 p.m., Monday through Friday.

F. NRC or Agreement State Concurrence

Several commenters objected to the provision in § 765.21(d) of the proposed rule requiring NRC or Agreement State concurrence in the reimbursement claim

approval process. These commenters asserted that involving the NRC or Agreement States in the process will cause undue delay. Furthermore, commenters argued that the Department's review will be adequate because of the Department's experience with UMTRCA Title I sites and because approved reclamation plans, or other written authorization for both pre- and post-UMTRCA costs, will be submitted to support claims for reimbursement. Some commenters argued that NRC or Agreement State concurrence is unnecessary for those claims that fall clearly within the scope of an approved plan or license condition. However, another commenter strongly supported the requirement for written certification from NRC or an Agreement State that claims be substantially in conformance with NRC or Agreement State authorization.

As discussed elsewhere in this preamble, section 1004(3) of the Act (42 U.S.C. 2296a–3(3)) requires that remedial action costs for which reimbursement is claimed must be for work "necessary to comply with all applicable requirements" of UMTRCA or, where appropriate, with applicable requirements established by an Agreement State. Whether work is necessary to comply with UMTRCA or Agreement State requirements often may be determined, at least in part, by a review of a site's approved reclamation plan or other written authorization. Licensees are required to link each cost of remedial action for which reimbursement is claimed to a specific element or activity contained in an approved reclamation plan or other NRC or Agreement State authorization for both pre- and post-UMTRCA costs. This will facilitate the Department's review of claims, and help to ensure that reimbursement is made only for costs incurred for activities necessary to comply with UMTRCA or, where appropriate, with applicable Agreement State requirements.

There may be situations, nevertheless, where the Department's review of the site's reclamation plan or other written authorization does not confirm that an activity for which reimbursement is claimed was necessary to comply with UMTRCA or, where appropriate, Agreement State requirements. To address these situations, § 765.21(d) of the proposed rule provided that before approving a claim for reimbursement, the Department would request NRC or the Agreement State to review the claim and provide written concurrence that the activities for which reimbursement is claimed are "substantially in conformance with the licensee's approved reclamation plan."

In response to the concerns raised by commenters, however, the Department has revised the requirement for NRC or Agreement State written concurrence. When it is not clear from a comparison of a claim and the approved site reclamation plan or other written authorization that an activity for which reimbursement is sought was necessary to comply with UMTRCA or, where appropriate, with applicable Agreement State requirements, the Department will consult with the appropriate regulatory authority to determine whether the activity was necessary to comply with these requirements.

In addition, some commenters urged that § 765.21(c) of the rule explicitly provide licensees with a right to attend and participate in informal conferences between Department and NRC or Agreement State personnel concerning a claim for reimbursement. The Department has decided not to adopt this approach. The claim submittal and review process provide a licensee with ample opportunity to present any relevant information or clarification necessary for the Department to be fully informed in reviewing and acting upon a claim. In addition, the Department may, at its discretion, provide a licensee with additional opportunities to clarify any issues which could arise with regard to a claim prior to reaching a final decision. However, to conform with the above revision to § 765.21(d) the Department has deleted the reference to the informal conference with NRC or an Agreement State in § 765.20(c). Any informal conference would be conducted as part of the Department's consultation with these regulatory agencies pursuant to §765.21(d).

G. Reimbursement of Costs of Subsequent Remedial Action

Section 765.30 of the proposed rule required licensees seeking reimbursement of costs after December 31, 2002 to submit a subsequent plan for remedial action to the Department in accordance with section 1001(b)(1)(B)(ii) of the Act. Specifically, reimbursement of costs incurred after December 31, 2002 would be subject to Department's approval of a plan containing: (1) Applicable remedial action requirements established by NRC or an Agreement State pursuant to UMTRCA that had not yet been satisfied by the licensee; and (2) the total cost of remedial action required at the site, with supporting documentation, segregated into actual costs incurred and anticipated future costs.

Several commenters indicated that the proposed rule provided inadequate guidance on the criteria the Department will use in approving a subsequent plan for remedial action. Specifically, these commenters construed proposed § 765.30(c) to mean that the Department would, if necessary, require a licensee to make changes to a reclamation plan approved by NRC or an Agreement State. In addition, some of these commenters claimed that the Department's review should be limited to matters of schedule.

The Department did not intend the proposed rule to require a licensee to make any changes to a reclamation plan approved by NRC or an Agreement State. On the other hand, the statutory authority to review and approve such plans is by no means limited to the scheduling of subsequent remedial action. To clarify the scope and purpose of this review, § 765.30(c) has been revised to state that the intended purpose of the Department's review is to determine conformance with an NRC- or Agreement State-approved reclamation plan, as well as the reasonableness of anticipated future costs.

Several commenters requested that the Department clarify in § 765.30(b) of the proposed rule the time in which it would approve a subsequent plan for remedial action which was previously rejected by the Department and modified by a licensee.

The final rule has been revised to provide that a licensee may continue to resubmit a subsequent plan for remedial action until the Department approves the plan or September 30, 2002, whichever date is earlier. This deadline for submission of plans provides sufficient time for a licensee to resubmit such a plan. It also allows the Department sufficient time to review and approve the plan and to designate by December 31, 2002 available amounts deposited in the Uranium Enrichment Decontamination and Decommissioning Fund, an escrow account established at the United States Treasury Department pursuant to section 1801 of the Act (42 U.S.C. 2297(g)), for reimbursement.

Some of these commenters requested that the Department allow for the reimbursement of remedial action costs incurred after December 31, 2002 for plans which have been submitted, but not yet approved by the Department, before this date. The Department does not have statutory authority to reimburse licensees for costs of remedial action after December 31, 2002 for which a plan has not been approved. Therefore, the final rule does not allow for the reimbursement of remedial costs

incurred after December 31, 2002, for those plans which have not been approved by this date.

One commenter questioned how the Department intends to address costs incurred prior to December 31, 2002, but not yet approved by the Department at the time the plan is submitted by the licensee.

To ensure that all incurred and future costs of remedial action are included in a subsequent plan for remedial action, the Department has revised § 765.30(b)(2) to include a third category of costs: Those costs incurred or expected to be incurred prior to December 31, 2002. This category includes those costs incurred prior to December 31, 2002 but not yet submitted in a claim for reimbursement, or approved by the Department.

Finally, many commenters requested that §§ 765.20(e) and 765.30(b)(2) of the proposed rule eliminate the provision that claims for reimbursement will be reviewed by the Department to assure that the costs are consistent with the surety requirements provided by the licensees to NRC or an Agreement State. These commenters argued that there are many significant differences between the anticipated costs upon which the surety requirements are based and the anticipated costs contained in plans for subsequent remedial action. These commenters also noted that in some circumstances the surety may not take into consideration all costs that may be reimbursed under Title X.

The Department acknowledges these concerns and has eliminated the surety requirement in the final rule. To conform with this change, the Department has deleted the definition of "surety requirements" contained in § 765.3 of the proposed rule.

H. Actions Subject to Appeals Procedures

Section 765.22 of the proposed rule provided procedures for appealing the Department's determination concerning the total dry short tons of byproduct material quantity and Federal-related dry short tons of byproduct material quantity present at a site. Although proposed § 765.22 provided licensees the opportunity to appeal the Department's dry short tons of byproduct material quantity determination, several commenters argued that proposed § 765.10(b), which required a licensee to either concur with the Department's determination or waive or exhaust its right of appeal prior to submitting a claim for reimbursement, effectively forced licensees to forego their right of appeal to obtain timely reimbursement. These commenters expressed concern that licensees would be unfairly penalized if denied reimbursement during the potentially lengthy appeals period.

The Department agrees with these commenters and has eliminated the requirement that a licensee waive its right of appeal with respect to a quantity determination of dry short tons of byproduct material prior to submitting a claim. However, in order to define the Federal reimbursement ratio that the Department will use to calculate reimbursement, the Department must, prior to providing any reimbursement to a licensee, make a determination concerning the total and Federal-related dry short tons of byproduct material quantities present at each site on October 24, 1992. Therefore, although under the final rule a licensee may submit a claim for reimbursement while appealing the Department's dry short tons of byproduct material quantity determination, the appeal must be made within 45 days after receiving notice of such determination. The 45-day limit provides a licensee with the right to appeal without foregoing the right to timely reimbursement and helps ensure that the Department is able to make the determinations necessary for orderly administration of the reimbursement program.

Under § 765.10(b), the Department's dry short tons of byproduct material quantity determinations will be used to calculate that portion of an approved claim that will be reimbursed. If the licensee's appeal of the Department's initial determination is successful, the difference between the initial quantity determination and that established by the appeals process will be paid to the licensee.

Some commenters noted that the proposed rule did not provide a licensee an opportunity to appeal the Department's decision concerning plans for subsequent remedial action, as well as other determinations required by this rule. This omission in the proposed rule was unintentional. Section 765.22 has been revised and streamlined in the final rule to allow appeals of any Department determination required by this rule, including a decision to reject or modify a plan for subsequent remedial action. While the decision to appeal a Department determination associated with this rule lies in the discretion of each eligible licensee, the rule requires that any appeal comply with the appeals process specified in § 765.22.

I. Miscellaneous Comments

Under § 765.3 of the proposed rule, the definition of "offsite disposal" refers to disposal of byproduct material from the sole existing thorium mill site pursuant to a plan approved by, or written authorization from, the Illinois Department of Nuclear Safety or other appropriate state agency. One commenter urged that the specific reference to the Illinois Department of Nuclear Safety be deleted from the definition in the event of a name change or revision of responsibilities of that agency, and the definition also include approvals and authorizations from the NRC. The Department has determined that the language of Title X does not limit reimbursement for offsite disposal to activities required by a specific state regulatory authority. Therefore, the definition of "offsite disposal" in the final rule has been modified to include activities required by the NRC or the State of Illinois.

Another commenter suggested that the Department consider making partial provisional advance payments to licensees, subject to an audit of expenditures. The Department does not have the statutory authority to make partial provisional advance payments.

A number of commenters suggested that the Department clarify how available funds will be disbursed if there are insufficient funds for full payment of all claims. Language in the proposed rule did not explicitly specify the priority for disbursement of funds among claims submitted by different review submission deadlines established by the Department. The final rule has been revised to specify that, if funds available are insufficient to make full payment in any given review cycle, all outstanding approved claims will be reimbursed on a prorated basis, regardless of when the claims were submitted or approved. This approach is consistent with the requirement of Title X that reimbursements be made to licensees at least annually.

Commenters also requested that claims be processed and paid twice a year. Title X requires that licensees be reimbursed at least annually. Therefore, the Department intends to provide payments to the licensees on at least an annual basis, but the Department is not prepared to commit in the rule to a more frequent reimbursement schedule.

The Department has modified § 765.20(a) and (d) of the proposed rule to clarify that the claim submission deadline(s) for a given year will be announced in the **Federal Register** shortly after the annual appropriation of funds by the Congress. To ensure an equitable distribution of annual appropriations, DOE will make payments for approved costs of remedial

action from the Fund within one year of the claim submission deadline.

Some commenters also urged the Department to modify the proposed rule's application of the inflation index adjustment provided in § 765.12 for claims approved for reimbursement. Some commenters argued that claims for reimbursement should be adjusted for inflation from the date the costs were incurred until the date of reimbursement. Others thought that an inflation adjustment should be made for the period between the submission or approval of a claim and the date of reimbursement.

Section 1001(b)(2)(D) of the Act (42 U.S.C. 2296(a)(b)(2)(D)) specifies the authority provided to the Department to adjust certain amounts for inflation. While the Secretary is given discretion to determine the appropriate inflation index to apply, this section dictates the amounts that are subject to adjustment for inflation. Congress explicitly and unequivocally limited the application of the inflation index to "the amounts in subparagraphs (A), (B), and (C) of this paragraph [section 1001(b)(2) of the Act]" (42 U.S.C. 2296a(b)(2)(D)). The amounts in subparagraphs (A), (B), and (C) of paragraph 1001(b)(2) are $5.50, $270,000,000, and $40,000,000, respectively. The Department is not authorized to adjust for inflation any claims for reimbursement. As a result, the approach taken in the proposed rule has been retained in the final rule.

In addition to the revisions discussed above, the Department also made minor clarifying or editorial changes to the proposed rule which are not specifically discussed in this preamble.

III. Section-By-Section Analysis

A. Subpart A—General

1. Section 765.1 Purpose

Section 765.1 specifies that the purpose of this rule is to establish procedures and requirements governing the reimbursement of remedial action costs authorized by Title X of the Act. The section confirms that the rule is promulgated as required by section 1002 of the Act (42 U.S.C. 2296a–1).

2. Section 765.2 Scope and Applicability

Section 765.2 describes the general scope and applicability of the rule. In particular, the section provides that reimbursements shall be made to a licensee of an active uranium or thorium processing site for costs of decontamination, decommissioning, reclamation, or other remedial action, which are supported by reasonable documentation and determined by the Department to be attributable to byproduct material generated as an incident of sales to the United States. Costs of decontamination, decommissioning, reclamation, and other remedial action must be for work that is necessary to comply with the requirements of UMTRCA or, where appropriate, with applicable requirements established by an Agreement State. Moreover, except as provided by § 765.32, reimbursement of a uranium site licensee shall be limited to $5.50, as adjusted for inflation, per Federal-related dry short ton of byproduct material. The total reimbursement paid to all uranium licensees shall not exceed $270 million, as adjusted for inflation. Reimbursement of the thorium site licensee shall not exceed $40 million, as adjusted for inflation.

3. Section 765.3 Definitions

Section 765.3 defines the acronyms and key terms used in the rule. Many of the definitions contained in § 765.3 are taken verbatim, or with minor changes, from Title X, UMTRCA, or the Atomic Energy Act. Additional definitions, discussed below, were developed specifically for this rule.

The term "active uranium or thorium processing site" or "active processing site" means:

(1) any uranium or thorium processing site, including the mill, containing byproduct material for which a license, issued either by NRC or by an Agreement State, for the production at such site of any uranium or thorium derived from ore—

(i) was in effect on January 1, 1978;

(ii) was issued or renewed after January 1, 1978; or

(iii) for which an application for renewal or issuance was pending on, or after January 1, 1978; and

(2) any other real property or improvement on such real property that is determined by the Secretary or by an Agreement State to be:

(i) in the vicinity of the site; and

(ii) contaminated with residual byproduct material.

The term "Agreement State" means a State that is or has been a party to a discontinuance agreement with NRC under section 274 of the Atomic Energy Act (42 U.S.C. 2021) and thereafter issues licenses and establishes remedial action requirements pursuant to a counterpart to section 62 or 81 of the Atomic Energy Act under state law.

The term "Atomic Energy Act" means Atomic Energy Act of 1954, as amended, (42 U.S.C. 2011 *et seq.*).

The term "byproduct material" means the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

The term "claim for reimbursement" is defined as the submission of an application for reimbursement in accordance with the requirements established in subpart C of this rule.

The term "costs of remedial action" means costs incurred by a licensee prior to or after enactment of UMTRCA to perform decontamination, decommissioning, reclamation, or other remedial action. These costs must be substantiated by documentation in accordance with the requirements of Subpart C of the rule. Costs of remedial action may include, but are not limited to, ground water remediation, treatment or containment of contaminated soil, disposal of process wastes, removal actions, air pollution abatement measures, mill and equipment decommissioning, site monitoring, administrative activities directly related to remedial action, expenditures required to meet necessary regulatory standards, and other costs for activities necessary to comply with the requirements of UMTRCA or applicable requirements established by an Agreement State.

The term "decontamination, decommissioning, reclamation, and other remedial action" means work performed which is necessary to comply with all applicable requirements of UMTRCA or, where appropriate, with applicable requirements established by an Agreement State.

The term "Department" means the United States Department of Energy or its authorized agents.

The term "dry short ton of byproduct material" is defined as the quantity of tailings generated from the extraction and processing of 2,000 pounds of uranium or thorium ore-bearing rock.

The term "Federal reimbursement ratio" means the ratio of Federal-related dry short tons of byproduct material to total dry short tons of byproduct material present at an active uranium or thorium processing site on October 24, 1992. The ratio shall be established by comparing Federal-related dry short tons of byproduct material to dry short tons of total byproduct material present at the site on October 24, 1992, or by another means of attributing costs of remedial action to byproduct material generated as an incident of sales to the United States which the Department determines is more accurate than a ratio established using dry short tons.

The term "Federal-related dry short ton(s) of byproduct material" is defined as the dry short ton(s) of byproduct material present at the site on October

24, 1992 that was generated as an incident of sales to the United States.

The term "generally accepted accounting principles" means those principles established by the Financial Accounting Standards Board which encompass the conventions, rules, and procedures necessary to define accepted accounting practice at a particular time.

The term "inflation index" is defined as the consumer price index for all urban consumers (CPI–U) as published by the Department of Commerce's Bureau of Labor Statistics.

The term "licensee" includes any site owner licensed under section 62 or 81 of the Atomic Energy Act by either NRC, or an Agreement State.

The terms "maximum reimbursement amount or maximum reimbursement ceiling" means the smaller of the following two quantities: (1) The amount obtained by multiplying the total cost of remedial action at the site, as determined in the approved plan for subsequent remedial action, by the Federal reimbursement ratio established for the site; or (2) $5.50, as adjusted for inflation, multiplied by the number of Federal-related dry short tons of byproduct material.

The term "NRC" means the United States Nuclear Regulatory Commission or its predecessor agency.

The term "offsite disposal" is defined as the decontamination, decommissioning, reclamation and other remedial action associated with disposal of byproduct material in a location not contiguous to the West Chicago Thorium Mill Site. This includes activities required by the State of Illinois, or NRC provided these activities are consistent with the ultimate removal of byproduct material from the West Chicago Thorium Mill Site.

The term "plan for subsequent remedial action" is defined as a plan approved by the Department, which includes an estimated total cost for remedial action and all applicable requirements of remedial action established by NRC or an Agreement State to be performed after December 31, 2002 at an active uranium or thorium processing site.

The terms "reclamation plan" or "site reclamation plan" means a plan approved by NRC or an Agreement State that establishes the work necessary to comply with UMTRCA or where appropriate applicable Agreement State requirements.

The term "remedial action" means decontamination, decommissioning, reclamation, and other remedial action at an active uranium or thorium processing site.

The term "Secretary" means the Secretary of Energy or her designees.

The term "site owner" is defined as a person that presently holds, or held in the past, any interest in land, including but not limited to a fee simple absolute, surface or subsurface ownership of mining claims, easements, and a right of access for the purposes of cleanup, or any other legal or equitable interest.

The term "tailings" is defined as the remaining portion of a metal-bearing ore after some or all of the metal, such as uranium, has been extracted.

The term "the Fund" means the Uranium Enrichment Decontamination and Decommissioning Fund established at the United States Department of Treasury pursuant to section 1801 of the Atomic Energy Act (42 U.S.C. 2297g).

The term "Title X" or "the Act" means Subtitle A of Title X of the Energy Policy Act of 1992, Pub. L. 102–486, 106 Stat. 2776 (42 U.S.C. 2296a–1 *et seq.*).

The term "UMTRCA" means the Uranium Mill Tailings Radiation Control Act of 1978, as amended (42 U.S.C. 7901 *et seq.*).

The term "United States" means any executive department, commission, or agency, or other establishment in the executive branch of the Federal Government.

The term "written authorization" means a written statement from either the NRC or an Agreement State that a licensee has performed in the past, or is authorized to perform in the future, a remedial action that is necessary to comply with the requirements of UMTRCA, or where appropriate with applicable Agreement State requirements.

B. Subpart B—Reimbursement Criteria

1. Section 765.10 Eligibility for Reimbursement

Section 765.10 outlines the basic eligibility requirements governing reimbursement. In particular, as required by section 1001 of the Act (42 U.S.C. 2296a), § 765.10 specifies that licensees shall be eligible for reimbursement of certain costs of remedial action, subject to the procedures and limitations specified in this rule.

Section 765.10(a) of the rule provides that costs of remedial action attributable to byproduct material generated as an incident of sales to the United States are reimbursable. Section 765.10(b) states that prior to reimbursement, the Department must determine the number of total dry short tons of byproduct material present at the site on October 24, 1992 and Federal-related dry short tons of byproduct material. This section provides that these determinations are subject to the appeals procedures specified in the rule. Provisions are made concerning reimbursement in the event of an appeal.

2. Section 765.11 Reimbursable Costs

Section 765.11 defines the requirements that a licensee must meet to be reimbursed for costs of remedial action at its active uranium or thorium processing site. Reimbursable costs of remedial action must be incurred prior to December 31, 2002, or be in accordance with a plan for subsequent remedial action approved by the Department. These costs of remedial action shall be reimbursed only if supported by reasonable documentation and approved by the Department in accordance with this rule. This documentation must demonstrate that the costs of remedial action incurred by a licensee are necessary to comply with applicable requirements of UMTRCA, or, where appropriate, with requirements established by an Agreement State. These requirements are contained in a reclamation plan, or other written authorization, issued or approved by NRC or an Agreement State, for work performed prior to or after enactment of UMTRCA. In addition, costs of remedial action are reimbursable only if the Department determines that they are attributable to byproduct material generated as an incident of sales to the United States and present at the site on October 24, 1992. These costs are equal to the total costs of remedial action at a site multiplied by the Federal reimbursement ratio established for the site, and approved by the Department for reimbursement.

Section 765.11 limits the amount of reimbursement paid to any one licensee of an active uranium processing site to an amount not to exceed $5.50, as adjusted for inflation, multiplied by the number of Federal-related dry short tons of byproduct material. Total reimbursement in the aggregate of uranium site licensees is limited to $270 million, as adjusted for inflation. Reimbursement of costs of remedial action at the eligible thorium processing site may only be made for costs incurred for offsite disposal, and is limited to $40 million, as adjusted for inflation.

3. Section 765.12 Inflation Index Adjustment Procedures

Title X directs the Department to determine an appropriate inflation index by which to increase annually (1) The $5.50 per dry short ton of byproduct material limit on

reimbursement to individual uranium site licensees, (2) the amount of $270 million authorized for payment to active uranium processing site licensees, (3) the amount of $40 million authorized for payment to the active thorium processing site licensee, and (4) the aggregate amount of $310 million authorized for payment to all licensees by Title X. As discussed elsewhere in this preamble, the Department intends to use the Consumer Price Index-Urban (CPI–U) as the appropriate inflation index for these adjustments. Section 765.12 of the rule provides that the CPI–U will be used to adjust these amounts annually beginning in 1994, to account for inflation that occurred in the previous calendar year.

C. Subpart C—Procedures for Filing and Processing Reimbursement Requests

Subpart C establishes the procedures for preparing and processing reimbursement claims. These procedures are designed to ensure that all information the Department needs to review a claim is made available to the Department, that claims are evaluated on a consistent basis, and that claims are processed in an efficient and equitable manner.

1. Section 765.20 Reimbursement Request Filing Procedures

Section 765.20 of the rule establishes the filing procedures, content, and format that a licensee must follow when submitting a claim for reimbursement. Each claim for reimbursement of remedial action costs must be supported by reasonable documentation.

A copy of the licensee's approved reclamation plan or other written authorization from NRC or an Agreement State must be submitted with the initial claim. Any revisions to this plan or authorization by NRC or an Agreement State must be submitted with the next claim prepared following approval of the revision. Each claim must provide a summary of all costs of remedial action for which reimbursement is claimed. The summary of costs must identify the pre- and post-UMTRCA costs associated with each major activity or requirement established by the site's reclamation plan or other written authorization.

The claim for reimbursement must also include a summary of the documentation available to support the claim. All summary documentation used in support of a claim must be cross-referenced to the relevant page and activity of the licensee's reclamation plan or other written authorization for pre- and post-UMTRCA costs. All documentation used in support of a claim must be made accessible to the Department, and the documentation should demonstrate that each cost for which reimbursement is claimed was incurred for a pre- or post-UMTRCA specific activity included in a reclamation plan or other written authorization, approved by NRC or an Agreement State. Where available, invoices, payroll records, receipts, and other documents should be used by the licensee to support claims for reimbursement. The rule requires licensees to utilize documents that were prepared contemporaneous to the time the cost which they support was incurred, whenever these documents are available. Documents prepared substantially after the cost was incurred will be considered by the Department in reviewing claims if that documentation is the only means available to document costs for which reimbursement is sought. The Department may audit, or require a licensee to audit, any documentation used to support a claim on a case-by-case basis and will exercise its discretion in determining the weight to accord to various supporting documents.

2. Section 765.21 Processing Reimbursement Requests

Section 765.21 outlines the procedures to be followed by the Department in processing each claim for reimbursement.

Sections 765.21 (a)–(c) provide that the Department will conduct a preliminary review of each claim within 60 days of the claim submittal deadline to determine if additional information is necessary. The Department may audit documentation used in support of the claim or request additional information or clarification necessary to verify any information provided by the licensee in a claim for reimbursement. In addition, the Department may request an informal conference with the applicant and, if necessary, with NRC or an Agreement State, to obtain information or clarification concerning any aspect of a claim. While the applicant is not required to provide additional information or clarification requested by the Department, a failure to do so may result in the denial of that portion of the claim for which information is requested.

The Department will conduct a final review of all relevant information to make a reimbursement decision. The Department will notify the claimant of its decision regarding a claim within 10 days of completing the final review.

Sections 765.21 (f)–(g) discuss the timing for processing and for payment of reimbursement requests. Reimbursements will be made on a prorated basis if there are insufficient funds available to reimburse all claims in full. Amounts not initially disbursed will be paid on a prorated basis, until satisfied in full, as funds become available. All outstanding, approved claims will be paid on the same prorated basis, regardless of when the claim was submitted or approved. Payments will be provided from the Fund, as required by the Act. Payment or obligation of funds shall be subject to the requirements of the Anti-Deficiency Act (31 U.S.C. 1341) as specified by § 765.21(g) of this rule. Following each annual appropriation by Congress, the Department will issue a Federal Register notice informing licensees of the availability of funds for reimbursement and whether the Department anticipates that approved claims for that year may be subject to prorated payment.

Section 765.21(h) requires an officer or other authorized official of a licensee to certify the accuracy of a claim for reimbursement, and subjects the individual making the certification to Federal statutes which provide civil and criminal penalties for making false claims.

3. Section 765.22 Appeals Procedures

Section 765.22 requires a licensee to utilize the Department's administrative appeals process (see 10 CFR part 205, subpart H) to appeal any Department determination required by this rule, including decisions that: (1) Determine tailings quantities of dry short tons of byproduct material or the Federal reimbursement ratio; (2) deny, in whole or in part, any claim for reimbursement; or (3) require modification of or reject a plan for subsequent remedial action. Any appeal must be filed with the Department's Office of Hearing and Appeals (hereinafter "OHA") within 45 days after the licensee receives notice, actual or constructive, (*i.e.*, by a publication in the **Federal Register**) of the Department's determination. OHA is a quasi-judicial body that reports to the Secretary of Energy and, except as otherwise provided by law, is responsible for conducting informal adjudicative proceedings of the Department, where there is a provision for separation of function. In connection with these duties, OHA holds hearings, receives evidence, develops a record, and issues a final determination, which is the Department's final decision, subject to review in the federal courts. A licensee must file an appeal in order to exhaust its administrative remedies, and the receipt of an OHA decision is a prerequisite to seeking judicial review

of any determination made under this Part.

4. Section 765.23 Annual Report

The Department will prepare an annual report, available to the public, summarizing pertinent information from the preceding year regarding the reimbursement program. The information may include, but not be limited to, individual and aggregate reimbursement claims approved and paid, approval of plans for subsequent remedial action, completion of particular elements of remedial action at active sites, total amounts paid and remaining for reimbursement, and other information. Licensees should be aware that any information submitted in a claim for reimbursement may be subject to public disclosure, through the annual report as well as by specific request, in accordance with the Freedom of Information Act (5 U.S.C. 552) and all other applicable requirements.

Subpart D—Additional Reimbursement Procedures

1. Section 765.30 Reimbursement of Costs Incurred in Accordance with a Plan for Subsequent Remedial Action

Section 765.30 of Subpart D establishes procedures for reimbursement of costs incurred in accordance with a plan for subsequent remedial action approved by the Department.

Reimbursement of costs incurred after December 31, 2002 shall be subject to the submission by the licensee of a plan for subsequent remedial action and approval of the plan by the Department. Each licensee seeking reimbursement of costs of remedial action to be incurred after December 31, 2002 shall submit their plan to the Department for its review and approval at any time between January 1, 2000 and December 31, 2001. The plan must include an estimated total cost and schedule for remedial action as well as all applicable requirements of remedial action established by NRC or an Agreement State to be performed after December 31, 2002 at an active uranium or thorium processing site. Each licensee will be required to provide reasonable documentation or other information to support its estimate of costs to be incurred.

The Department may approve, approve with modification, or reject any plan submitted by a licensee. At any time following submittal of a plan, the Department may request additional information from the licensee, and may consult with NRC or an Agreement State concerning remaining remedial action requirements contained in the site's approved reclamation plan. If the Department rejects a plan, the licensee may file an appeal pursuant to § 765.22 or submit revised plans for review by the Department, until a plan is approved, or until September 30, 2002, whichever occurs first. The Department has established September 30, 2002, as the deadline for submission of any potential revised plans so that the Department will have sufficient time to review the submittals and designate available amounts on deposit in the Fund for reimbursement by December 31, 2002 consistent with section 1001(b)(1)(B)(ii) of the Act (42 U.S.C. 2296a(b)(1)(B)(ii)). A failure by a licensee to receive approval from the Department of a plan for subsequent remedial action prior to December 31, 2002 will preclude that licensee from receiving any reimbursement for costs incurred after that date. Costs incurred in accordance with the requirements of a plan for subsequent remedial action, and approved by the Department, will be reimbursed in an amount equal to the approved cost multiplied by the site's Federal reimbursement ratio, until such time as the Department determines that its obligation under Title X to reimburse the licensee has been satisfied.

2. Section 765.31 Designation of Funds Available for Subsequent Remedial Action

Section 765.31 establishes procedures for reimbursement of costs incurred in accordance with an approved plan(s) for subsequent remedial action.

Upon approval of each plan submitted by a licensee, and subject to the availability of appropriated funds and the requirements of the Anti-Deficiency Act (31 U.S.C. 1341), the Department will designate amounts deposited in the Fund at the United States Department of Treasury, established pursuant to section 1801 of the Atomic Energy Act (42 U.S.C. 2297g), to reimburse a licensee for estimated costs of remedial action in implementing a Department-approved plan for subsequent remedial action.

3. Section 765.32 Reimbursement of Excess Funds

Section 1001(b)(2)(E)(i) of the Act (42 U.S.C. 2296a(b)(2)(B)(i)) authorizes the Department to determine, as of July 31, 2005, whether the aggregate amount authorized to be appropriated by section 1003 of the Act (42 U.S.C. 2296a–2) when considered with the $5.50 per dry short ton limit on reimbursement, as adjusted for inflation, for active uranium processing site licensees, exceeds the amount reimbursable to licensees under section 1001(b)(2) of the Act (42 U.S.C. 2296a(b)(2)). If any active uranium processing site licensee incurs reimbursable costs in excess of $5.50 per dry short ton limit on reimbursement, and the Department has determined that excess funds exist as of July 31, 2005, section 1001(b)(2)(E)(ii) of the Act (42 U.S.C. 2296a(b)(2)(E)(ii)) authorizes the Department to provide reimbursement of those costs on a prorated basis to the extent funds are available.

Section 765.32 outlines the procedures that would govern any additional reimbursement.

IV. Review Under Executive Order 12866

Today's regulatory action has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, today's action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs.

V. Review Under the Regulatory Flexibility Act

This rule was reviewed under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The Regulatory Flexibility Act requires that a regulatory flexibility analysis be performed for all rules that are likely to have "significant impact on a substantial number of small entities." This rule involves reimbursement for costs of remedial action at active uranium and thorium processing sites. The number of potentially eligible applicants is very limited. Because this rule provides for reimbursement of funds authorized by Title X, it does not pose any adverse effect on the private sector economy or small entities, and in fact may provide a benefit to small entities located near active processing sites. The Department, therefore, certifies that this rule will not have a significant impact on a substantial number of small entities.

VI. Review Under the Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and have been assigned OMB control number 1910–1400.

VII. Review Under the National Environmental Policy Act

This rule establishes procedures for the reimbursement of eligible remedial action costs incurred by licensees at

active uranium or thorium processing sites. Implementation of this rule will result in cost reimbursement payments to eligible licensees, but will not affect the legally required cleanup of the sites or result in any other environmental impacts. The Department has therefore determined that this rule is covered under the Categorical Exclusion found at paragraph A6. of Appendix A to subpart D, 10 CFR part 1021, which applies to the establishment of procedural rulemakings such as procedures for the review and approval of applications for grants and cooperative agreements. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

VIII. Review Under Executive Order 12612

This rule does not have a substantial direct effect on the States, the relationship between the States and the Federal Government, or the distribution of power and responsibilities among various levels of government. Therefore, no federalism assessment under Executive Order 12612 is required.

IX. Review Under Executive Order 12778

Section 2 of Executive Order 12778 instructs agencies to adhere to certain requirements in promulgating new regulations and reviewing existing regulations. These requirements, set forth in sections 2(a) and (b), include eliminating drafting errors and needless ambiguity, drafting the regulations to minimize litigation, providing clear and certain legal standards for affected conduct, and promoting simplification and burden reduction. Agencies are also instructed to make every reasonable effort to ensure that the rule clearly specifies any preemptive effect, effect on existing Federal law or regulation, and retroactive effect; describes any administrative proceedings available prior to judicial review; any provisions for the exhaustion of administrative proceedings; and defines key terms. The Department certifies that today's rule meets the requirements of sections 2(a) and (b) of Executive Order 12778.

List of Subjects in 10 CFR Part 765

Radioactive materials, Reclamation, Reporting and recordkeeping requirements, Uranium.

Issued in Washington, DC, on this 10th day of May 1994.

Thomas P. Grumbly,

Assistant Secretary for Environmental Management.

For the reasons set out in the Preamble, Chapter III of Title 10 of the Code of Federal Regulations is amended by adding a new part 765 to read as follows:

PART 765—REIMBURSEMENT FOR COSTS OF REMEDIAL ACTION AT ACTIVE URANIUM AND THORIUM PROCESSING SITES

Subpart A—General

Sec.

Subpart B—Reimbursement Criteria

Subpart C—Procedures for Submitting and Processing Reimbursement Requests

Subpart D—Additional Reimbursement Procedures

Authority: Sections 1001–1004 of Pub. L. No. 102–486, 106 Stat. 2776 (42 U.S.C. 2296a *et seq.*).

Subpart A—General

765.1 Purpose.

The provisions of this Part establish regulatory requirements governing reimbursement for certain costs of remedial action at active uranium or thorium processing sites as specified by Subtitle A of Title X of the Energy Policy Act of 1992. These regulations are authorized by section 1002 of the Act (42 U.S.C. 2296a–1), which requires the Secretary to issue regulations governing the reimbursements.

765.2 Scope and applicability.

(a) This Part establishes policies, criteria, and procedures governing reimbursement of certain costs of remedial action incurred by licensees at active uranium or thorium processing sites as a result of byproduct material generated as an incident of sales to the United States.

(b) Costs of remedial action at active uranium or thorium processing sites are borne by persons licensed under section 62 or 81 of the Atomic Energy Act (42 U.S.C. 2092, 2111), either by NRC or an Agreement State pursuant to a counterpart to section 62 or 81 of the Atomic Energy Act, under State law, subject to the exceptions and limitations specified in this Part.

(c) The Department shall, subject to the provisions specified in this part, reimburse a licensee, of an active uranium or thorium processing site for the portion of the costs of remedial action as are determined by the Department to be attributable to byproduct material generated as an incident of sales to the United States and either incurred by the licensee not later than December 31, 2002, or incurred by the licensee in accordance with a plan for subsequent remedial action approved by the Department.

(d) Costs of remedial action are reimbursable under Title X for decontamination, decommissioning, reclamation, and other remedial action, provided that claims for reimbursement are supported by reasonable documentation as specified in Subpart C of this Part.

(e) Except as authorized by § 765.32, the total amount of reimbursement paid to any licensee of an active uranium processing site shall not exceed $5.50 multiplied by the number of Federal-related dry short tons of byproduct material. This total amount shall be adjusted for inflation pursuant to section 765.12.

(f) The total amount of reimbursement paid to all active uranium processing site licensees shall not exceed $270 million. This total amount shall be adjusted for inflation by applying the CPI–U, as provided by § 765.12.

(g) The total amount of reimbursement paid to the licensee of the active thorium processing site shall not exceed $40 million, as adjusted for inflation by applying the CPI–U as provided by § 765.12.

(h) Reimbursement of licensees for costs of remedial action will only be made for costs that are supported by reasonable documentation as required by § 765.20 and claimed for reimbursement by a licensee in accordance with the procedures established by Subpart C of this Part.

(i) The $310 million aggregate amount authorized to be appropriated under section 1003(a) of the Act (42 U.S.C. 2296a-2(a)) shall be adjusted for inflation by applying the CPI–U as provided by § 765.12, and shall be provided from the Fund.

§ 765.3 Definitions.

For the purposes of this Part, the following terms are defined as follows:

Active uranium or thorium processing site or *active processing site* means:

(1) any uranium or thorium processing site, including the mill, containing byproduct material for which a license, issued either by NRC or by an Agreement State, for the production at a site of any uranium or thorium derived from ore—

(i) was in effect on January 1, 1978;

(ii) was issued or renewed after January 1, 1978; or

(iii) for which an application for renewal or issuance was pending on, or after January 1, 1978; and

(2) any other real property or improvement on such real property that is determined by the Secretary or by an Agreement State to be:

(i) in the vicinity of such site; and

(ii) contaminated with residual byproduct material.

Agreement State means a State that is or has been a party to a discontinuance agreement with NRC under section 274 of the Atomic Energy Act (42 U.S.C. 2021) and thereafter issues licenses and establishes remedial action requirements pursuant to a counterpart to section 62 or 81 of the Atomic Energy Act under state law.

Atomic Energy Act means the Atomic Energy Act of 1954, as amended, (42 U.S.C. 2011 *et seq.*).

Byproduct material means the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

Claim for reimbursement means the submission of an application for reimbursement in accordance with the requirements established in Subpart C of this Part.

Costs of remedial action means costs incurred by a licensee prior to or after enactment of UMTRCA to perform decontamination, decommissioning, reclamation, and other remedial action. These costs may include but are not necessarily limited to expenditures for work necessary to comply with applicable requirements to conduct groundwater remediation, treatment or containment of contaminated soil, disposal of process wastes, removal actions, air pollution abatement measures, mill and equipment decommissioning, site monitoring, administrative activities, expenditures required to meet necessary regulatory standards, or other requirements established by NRC, or an Agreement State. Costs of remedial action must be supported by reasonable documentation in accordance with the requirements of Subpart C of this Part.

Decontamination, decommissioning, reclamation, and other remedial action means work performed which is necessary to comply with all applicable requirements of UMTRCA or, where appropriate, with applicable requirements established by an Agreement State.

Department means the United States Department of Energy or its authorized agents.

Dry short tons of byproduct material means the quantity of tailings generated from the extraction and processing of 2,000 pounds of uranium or thorium ore-bearing rock.

Federal reimbursement ratio means the ratio of Federal-related dry short tons of byproduct material to total dry short tons of byproduct material present at an active uranium or thorium processing site on October 24, 1992. The ratio shall be established by comparing Federal-related dry short tons of byproduct material to total dry short tons of byproduct material present at the site on October 24, 1992, or by another means of attributing costs of remedial action to byproduct material generated as an incident of sales to the United States which the Department determines is more accurate than a ratio established using dry short tons of byproduct material.

Federal-related dry short tons of byproduct material means dry short tons of byproduct material that was present at an active uranium or thorium processing site on October 24, 1992, and was generated as an incident of uranium or thorium sales to the United States.

Generally accepted accounting principles means those principles established by the Financial Accounting Standards Board which encompass the conventions, rules, and procedures necessary to define accepted accounting practice at a particular time.

Inflation index means the consumer price index for all urban consumers (CPI–U) as published by the Department of Commerce's Bureau of Labor Statistics.

Licensee means a site owner licensed under section 62 or 81 of the Atomic Energy Act (42 U.S.C. 2092, 2111) by NRC, or an Agreement State, for any activity at an active uranium or thorium processing site which results, or has resulted, in the production of byproduct material.

Maximum reimbursement amount or maximum reimbursement ceiling means the smaller of the following two quantities:

(1) The amount obtained by multiplying the total cost of remedial action at the site, as determined in the approved plan for subsequent remedial action, by the Federal reimbursement ratio established for the site; or

(2) $5.50, as adjusted for inflation, multiplied by the number of Federal-related dry short tons of byproduct material.

NRC means the United States Nuclear Regulatory Commission or its predecessor agency.

Offsite disposal means the disposal, and activities that contribute to the disposal, of byproduct material in a location that is not contiguous to the West Chicago Thorium Mill Site located in West Chicago, Illinois, in accordance with a plan approved by, or other written authorization from, the State of Illinois or NRC provided the activities are consistent with the ultimate removal of byproduct material from the West Chicago Thorium Mill Site.

Plan for subsequent remedial action means a plan approved by the Department which includes an estimated total cost and schedule for remedial action, and all applicable requirements of remedial action established by NRC or an Agreement State to be performed after December 31, 2002 at an active uranium or thorium processing site.

Reclamation plan or site reclamation plan means a plan, which has been approved by NRC or an Agreement State, for remedial action at an active processing site that establishes the work necessary to comply with applicable requirements of UMTRCA, or where appropriate with requirements established by an Agreement State.

Remedial action means decontamination, decommissioning, reclamation, and other remedial action at an active uranium or thorium processing site.

Secretary means the Secretary of Energy or her designees.

Site owner means a person that presently holds, or held in the past, any interest in land, including but not limited to a fee simple absolute, surface or subsurface ownership of mining claims, easements, and a right of access for the purposes of cleanup, or any other legal or equitable interest.

Tailings means the remaining portion of a metal-bearing ore after some or all of the metal, such as uranium, has been extracted.

The Fund means the Uranium Enrichment Decontamination and Decommissioning Fund established at the United States Department of Treasury pursuant to section 1801 of the Atomic Energy Act (42 U.S.C. 2297g).

Title X or "the Act" means Subtitle A of Title X of the Energy Policy Act of

1992, Public Law 102–486, 106 Stat. 2776 (42 U.S.C. 2296a–1 *et seq.*).

UMTRCA means the Uranium Mill Tailings Radiation Control Act of 1978, as amended (42 U.S.C. 7901 *et seq.*).

United States means any executive department, commission, or agency, or other establishment in the executive branch of the Federal Government.

Written Authorization means a written statement from either the NRC or an Agreement State that a licensee has performed in the past, or is authorized to perform in the future, a remedial action that is necessary to comply with the requirements of UMTRCA or, where appropriate, the requirements of an Agreement State.

Subpart B—Reimbursement Criteria

§ 765.10 Eligibility for reimbursement.

(a) Any licensee of an active uranium or thorium processing site that has incurred costs of remedial action for the site that are attributable to byproduct material generated as an incident of sales to the United States shall be eligible for reimbursement of these costs, subject to the procedures and limitations specified in this Part.

(b) Prior to reimbursement of costs of remedial action incurred by a licensee, the Department shall make a determination regarding the total quantity of dry short tons of byproduct material, and the quantity of Federal-related dry short tons of byproduct material present on October 24, 1992 at the licensee's active processing site. A claim for reimbursement from a site for which a determination is made will be evaluated individually. If a licensee does not concur with the Department's determination regarding the quantity of dry short tons of byproduct material present at the site, the licensee may appeal the Department's determination in accordance with § 765.22 of this part. The Department's determination shall be used to determine that portion of an approved claim for reimbursement submitted by the licensee which shall be reimbursed, unless or until the determination is overturned on appeal. If the outcome of an appeal requires a change in the Department's initial determination, the Department will adjust any payment previously made to the licensee to reflect the change.

§ 765.11 Reimbursable costs.

(a) Costs for which a licensee may be reimbursed must be for remedial action that a licensee demonstrates is attributable to byproduct material generated as an incident of sales to the United States, as determined by the Department. These costs are equal to the total costs of remedial action at a site multiplied by the Federal reimbursement ratio established for the site. These costs must be incurred in the performance of activities, prior to or after enactment of UMTRCA, and required by a plan, portion thereof, or other written authorization, approved by NRC or by an Agreement State. Costs of remedial action shall be reimbursable only if approved by the Department in accordance with the provisions of this part.

(b) In addition, costs of remedial action incurred by a licensee after December 31, 2002 must be in accordance with a plan for subsequent remedial action approved by the Department as specified in § 765.30.

(c) Total reimbursement of costs of remedial action incurred at an active processing site that are otherwise reimbursable pursuant to the provisions of this Part shall be limited as follows:

(1) Reimbursement of costs of remedial action to active uranium processing site licensees shall not exceed $5.50, as adjusted for inflation, multiplied by the number of Federal-related dry short tons of byproduct material.

(2) Aggregate reimbursement of costs of remedial action incurred at all active uranium processing sites shall not exceed $270 million. This aggregate amount shall be adjusted for inflation pursuant to § 765.12; and

(3) Reimbursement of costs of remedial action at the active thorium processing site shall be limited to costs incurred for offsite disposal and shall not exceed $40 million. This amount shall be adjusted for inflation pursuant to § 765.12.

(d) Notwithstanding the Title X requirement that byproduct material must be located at an active processing site on October 24, 1992, byproduct material moved from the Edgemont Mill in Edgemont, South Dakota, to a disposal site as a result of remedial action, shall be eligible for reimbursement in accordance with all applicable requirements of this part.

§ 765.12 Inflation index adjustment procedures.

(a) The amounts of $5.50 (as specified in § 765.2(e) of this rule) $270 million (as specified in § 765.2(f) of this rule), $40 million (as specified in § 765.2(g) of this rule) and $310 million (as specified in § 765.2(i) of this rule) shall be adjusted for inflation as provided by this section.

(b) To make adjustments for inflation to the amounts specified in paragraph (a) of this section, the Department shall apply the CPI–U to these amounts annually, beginning in 1994, using the CPI–U as published by the Bureau of Labor Statistics within the Department of Commerce for the preceding calendar year.

(c) The Department shall adjust annually, using the CPI–U as defined in this Part, amounts paid to an active uranium processing site licensee for purposes of comparison with the $5.50 per dry short ton limit on reimbursement as adjusted for inflation.

Subpart C—Procedures for Submitting and Processing Reimbursement Claims

§ 765.20 Procedures for submitting reimbursement claims.

(a) All costs of remedial action for which reimbursement is claimed must be supported by reasonable documentation as specified in this subpart. The Department reserves the right to deny any claim for reimbursement, in whole or in part, that is not submitted in accordance with the requirements of this subpart.

(b) The licensee shall provide a copy of the approved site reclamation plan or other written authorization from NRC or an Agreement State upon which claims for reimbursement are based, with the initial claim submitted. Any revision or modification made to the plan or other written authorization, which is approved by NRC or an Agreement State, shall be included by the licensee in the next claim submitted to the Department following that revision or modification. This reclamation plan or other written authorization, as modified or revised, shall serve as the basis for the Department's evaluation of all claims for reimbursement submitted by a licensee.

(c) Each submitted claim shall provide a summary of all costs of remedial action for which reimbursement is claimed. This summary shall identify the costs of remedial action associated with each major activity or requirement established by the site's reclamation plan or other written authorization. In addition, each claim shall provide a summary of the documentation relied upon by the licensee in support of each cost category for which reimbursement is claimed.

(d) Documentation used to support a reimbursement claim must demonstrate that the costs of remedial action for which reimbursement is claimed were incurred specifically for activities specified in the site's reclamation plan, or otherwise authorized by NRC or an Agreement State. Summary documentation used in support of a

claim must be cross-referenced to the relevant page and activity of the licensee's reclamation plan, or other written authorization approved by NRC or an Agreement State.

(1) Documentation prepared contemporaneous to the time the cost was incurred should be used when available. The documentation should identify the date or time period for which the cost was incurred, the activity for which the cost was incurred, and the reclamation plan provision or other written authorization to which the cost relates. Where available, each claim should be supported by receipts, invoices, pay records, or other documents that substantiate that each specific cost for which reimbursement is claimed was incurred for work that was necessary to comply with UMTRCA or applicable Agreement State requirements.

(2) Documentation not prepared contemporaneous to the time the cost was incurred, or not directly related to activities specified in the reclamation plan or other written authorization, may be used in support of a claim for reimbursement provided that the licensee determines the documentation is the only means available to document costs for which reimbursement is sought.

(e) The Department may audit, or require the licensee to audit, any documentation used to support a claim on a case-by-case basis and may approve, approve in part, or deny reimbursement of any claim in accordance with the requirements of this part. Documentation relied upon by a licensee in support of a claim for reimbursement shall be made available to the Department and retained by the licensee until 4 years after final payment of a claim is made by the Department.

(f) Each licensee should utilize generally accepted accounting principles consistently throughout the claim. These accounting principles, underlying assumptions, and any other information necessary for the Department to evaluate the claim shall be set forth in each claim.

(g) Following each annual appropriation by Congress, the Department will issue a Federal Register Notice announcing:

(1) A claim submission deadline for that fiscal year;

(2) Availability of funds for reimbursement of costs of remedial action;

(3) Whether the Department anticipates that approved claims for that fiscal year may be subject to prorated payment;

(4) Any changes in the Federal reimbursement ratio or maximum reimbursement ceiling for any active uranium or thorium processing site;

(5) Any revision in the per dry short ton limit on reimbursement for all active uranium processing sites; and

(6) Any other relevant information.

(h) A licensee shall certify, with respect to any claim submitted by it for reimbursement, that the work was completed as described in an approved reclamation plan or other authorization. In addition, the licensee shall certify that all costs for which reimbursement is claimed, all documentation relied upon in support of its costs, and all statements or representations made in the claim are complete, accurate, and true. The certification shall be signed by an officer or other official of the licensee with knowledge of the contents of the claim and authority to represent the licensee in making the certification. Any knowingly false or frivolous statements or representations may subject the individual to penalties under the False Claims Act, sections 3729 through 3731 of title 31 United States Code, or any other applicable statutory authority; and criminal penalties under sections 286, 287, 1001 and 1002 of title 18, United States Code, or any other applicable statutory authority.

(i) All claims for reimbursement submitted to the Department shall be sent by registered or certified mail, return receipt requested. The Department reserves all rights under applicable law to recover any funds paid to licensees which an audit finds to not meet the requirements of this part.

§ 765.21 Procedures for processing reimbursement claims.

(a) The Department will conduct a preliminary review of each claim within 60 days after the claim submission deadline announced in the Federal Register Notice specified in § 765.20(g) to determine the completeness of each claim. Payments from the Fund to active uranium or thorium processing site licensees for approved costs of remedial action will be made simultaneously by the Department within 1 year of the claim submission deadline.

(b) After completing the preliminary review specified in paragraph (a) of this section, the Department may audit, or require the licensee to audit, any documentation used in support of such claim, request the licensee to provide additional information, or request the licensee to provide other clarification determined by the Department to be necessary to complete its evaluation of the claim. In addition, the Department reserves the right to conduct an inspection of the site to verify any information provided by the licensee in a claim for reimbursement, or in support thereof. Any information requested by the Department, if provided, must be submitted by the claimant within 60 days of receipt of the request unless the Department specifies in writing that additional time is provided.

(c) At any time during the review of a claim, the Department may request an informal conference with a licensee to obtain further information or clarification on any unresolved issue pertaining to the claim. While the licensee is not required to provide additional clarification requested by the Department, a failure to do so may result in the denial of that portion of the claim for which information is requested.

(d) Based upon the claim submitted and any additional information received by the Department, including any audit or site inspection if conducted, the Department shall complete a final review of all relevant information prior to making a reimbursement decision. When the Department determines it is not clear that an activity for which reimbursement is claimed was necessary to comply with UMTRCA or where appropriate, with applicable Agreement State requirements, the Department may consult with the appropriate regulatory authorities.

(e) A written decision regarding the Department's determination to approve, approve in part, or deny a claim will be provided to the licensee within 10 days of completion of the final review.

(f) If the Department determines that insufficient funds are available at any time to provide for complete payment of all outstanding approved claims, reimbursements of approved claims will be made on a prorated basis. A prorated payment of all outstanding approved claims for reimbursement, or any unpaid portion thereof, shall be made on the basis of the total amount of all outstanding approved claims, regardless of when the claims were submitted or approved.

(g) Notwithstanding the provisions of paragraph (f) of this section, or any other provisions of this part, any requirement for the payment or obligation of funds by the Department established by this part shall be subject to the availability of appropriated funds, and no provision herein shall be interpreted to require obligation or payment of funds in violation of the Anti-Deficiency Act (31 U.S.C. 1341).

§ 765.22 Appeals procedures.

(a) Any appeal by a licensee of any Department determination subject to the requirements of this part, shall invoke the appeals process specified in paragraph (b) of this section.

(b) A licensee shall file an appeal of any Department determination subject to the requirements of this part with the Office of Hearings and Appeals, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585. Any appeal must be filed within 45 days from the date the licensee received notice, actual or constructive (i.e., publication in the **Federal Register**), of the Department's determination. Appeals will be governed by, and must comply in full with, the procedures set forth in 10 CFR part 205, subpart H. The decision of the Office of Hearings and Appeals shall be the final decision of the Department. A licensee must file an appeal in order to exhaust its administrative remedies, and the receipt of an appellate decision is a prerequisite to seeking judicial review of any determination made under this part.

§ 765.23 Annual report.

The Department shall prepare annually a report summarizing pertinent information concerning claims submitted in the previous calendar year, the status of the Department's review of the claims, determinations made regarding the claims, amounts paid for claims approved, and other relevant information concerning this reimbursement program. The report will be available to all interested parties upon written request to the Department's Uranium Mill Tailings Remedial Action Project Office, 2155 Louisiana NE., suite 10000, Albuquerque, NM 87110 and will also be available in the Department's Freedom of Information Reading room, 1000 Independence Avenue SW., Washington, DC.

Subpart D—Additional Reimbursement Procedures

§ 765.30 Reimbursement of costs incurred in accordance with a plan for subsequent remedial action.

(a) This section establishes procedures governing reimbursements of costs of remedial action incurred in accordance with a plan for subsequent remedial action approved by the Department as provided in this section. Costs otherwise eligible for reimbursement in accordance with the terms of this part and incurred in accordance with the plan shall be reimbursed in accordance with the provisions of subpart D and subpart C. In the event there is an inconsistency between the requirements of subpart D and subpart C, the provisions of subpart D shall govern reimbursement of such costs of remedial action.

(b) A licensee who anticipates incurring costs of remedial action after December 31, 2002 may submit a plan for subsequent remedial action. This plan may be submitted at any time after January 1, 2000, but no later than December 31, 2001. Reimbursement of costs of remedial action incurred after December 31, 2002 shall be subject to the approval of this plan by the Department. This plan shall describe:

(1) All applicable requirements established by NRC pursuant to UMTRCA, or where appropriate, by the requirements of an Agreement State, included in a reclamation plan approved by NRC or an Agreement State which have not yet been satisfied in full by the licensee, and

(2) The total cost of remedial action required at the site, together with all necessary supporting documentation, segregated into actual costs incurred to date, costs incurred or expected to be incurred prior to December 31, 2002 but not yet approved for reimbursement, and anticipated future costs.

(c) The Department shall review the plan for subsequent remedial action to verify conformance with the NRC- or Agreement State-approved reclamation plan or other written authorization, and to determine the reasonableness of anticipated future costs, and shall approve, approve with suggested modifications, or reject the plan. During its review, the Department may request additional information from the licensee to clarify or provide support for any provision or estimate contained in the plan. The Department may also consult with NRC or an Agreement State concerning any provision or estimate contained in the plan. Upon approval, approval with modifications, or rejection of a plan, the Department shall inform and explain to the licensee its decision.

(d) If the Department rejects a plan for subsequent remedial action submitted by a licensee, the licensee may appeal the Department's rejection or prepare and submit a revised plan. The licensee may continue to submit revised plans for subsequent remedial action until the Department approves a plan, or September 30, 2002, whichever occurs first. A failure by a licensee to receive approval from the Department of a plan prior to December 31, 2002 will preclude that licensee from receiving any reimbursement for costs of remedial action incurred after that date.

(e) The Department shall determine, in approving a plan for subsequent remedial action, the maximum reimbursement amount for which the licensee may be eligible. This maximum reimbursement amount shall be the smaller of the following two quantities:

(1) The amount obtained by multiplying the total cost of remedial action at the site, as determined in the approved plan for subsequent remedial action, by the Federal reimbursement ratio established for such site; or

(2) $5.50, as adjusted for inflation, multiplied by the number of Federal-related dry short tons of byproduct material. The Department shall subtract from the maximum reimbursement amount any reimbursement already approved to be paid to the licensee. The resulting sum shall be the potential additional reimbursement to which the licensee may be entitled.

§ 765.31 Designation of funds available for subsequent remedial action.

(a) Upon the Department's approval of each plan for subsequent remedial action submitted by a licensee, the Department will designate specific amounts on deposit in the Fund for reimbursement, subject to the availability of appropriated funds as specified in § 765.21(g). If insufficient funds are available at the time of approval of a plan for subsequent remedial action to provide for reimbursement of the total estimated costs, the designation of specific amounts on deposit in the Fund for reimbursement will be made on a prorated basis. Any remaining balance will be designated for reimbursement at the time additional funds become available.

(b) The Department shall authorize reimbursement of costs of remedial action, incurred in accordance with an approved plan for subsequent remedial action and approved by the Department as specified in Subpart C to this Part, to be made from the Fund. These costs are reimbursable until:

(1) This remedial action has been completed, or

(2) The licensee has been reimbursed its maximum reimbursement amount as determined by the Department pursuant to paragraph (e) of § 765.30.

(c) A licensee shall submit any claim for reimbursement of costs of remedial action incurred pursuant to an approved plan for subsequent remedial action in accordance with the requirements of subpart C of this part. The Department shall approve, approve in part, or deny any claims in accordance with the procedures specified in subpart C of this part. The Department shall authorize the

disbursement of funds upon approval of a claim for reimbursement.

(d) After all remedial actions have been completed by affected Agreement State or NRC licensees, the Department will issue a Federal Register notice announcing a termination date beyond which claims for reimbursement will no longer be accepted.

§ 765.32 Reimbursement of excess funds.

(a) No later than July 31, 2005, the Department shall determine if the aggregate amount authorized for appropriation pursuant to section 1003 of the Act (42 U.S.C. 2296a–2), as adjusted for inflation pursuant to § 765.12, exceed as of that date the combined total of all reimbursements which have been paid to licensees under this part, any amounts approved for reimbursement and owed to any licensee, and any anticipated additional reimbursements to be made in accordance with approved plans for subsequent remedial action.

(b) If the Department determines that the amount authorized pursuant to section 1003 of the Act (42 U.S.C. 2296a–2), as adjusted for inflation, exceed the combined total of all reimbursements (as indicated in paragraph (a) of this section), the Department may establish procedures for providing additional reimbursement to uranium licensees for costs of remedial action, subject to the availability of appropriated funds. If the amount of available excess funds is insufficient to provide reimbursement of all eligible costs of remedial action, then reimbursement shall be paid on a prorated basis.

(c) Each eligible uranium licensee's prorated share will be determined by dividing the total excess funds available by the total number of Federal-related dry short tons of byproduct material present at the site where costs of remedial action exceed $5.50 per dry short ton, as adjusted for inflation pursuant to § 765.12. The resulting number will be the maximum cost per dry short ton, over $5.50, that may be reimbursed. Total reimbursement for each licensee that has incurred approved costs of remedial action in excess of $5.50 per dry short ton will be the product of the excess cost per dry short ton multiplied by the number of Federal-related dry short tons of byproduct material at the site or the actual costs incurred and approved by the Department, whichever is less.

(d) Any costs of remedial action for which reimbursement is sought from excess funds determined by the Department to be available is subject to all requirements of this part except the per dry short ton limit on reimbursement established by paragraph (d) of § 765.11.

[FR Doc. 94–12132 Filed 5–20–94; 8:45 am]

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DEPARTMENT OF ENERGY

Reimbursement for Costs of Remedial Action at Active Uranium and Thorium Processing Sites

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of the acceptance of claims and the availability of funds for reimbursements in fiscal year 1994.

SUMMARY: This Notice announces the Department of Energy's acceptance of initial claims and the availability of approximately $40.6 million in funds in fiscal year 1994 for reimbursements of certain costs of remedial action at eligible active uranium and thorium processing sites pursuant to Title X of the Energy Policy Act of 1992. The Department of Energy anticipates that claims submitted by licensees in fiscal year 1994 will substantially exceed $40.6 million and would therefore be subject to prorated payment.

DATES: The closing date for the submission of claims for reimbursement in fiscal year 1994 is July 7, 1994.

ADDRESSES: Claims may be mailed to the Uranium Mill Tailings Remedial Action Project Office, U.S. Department of Energy, 2155 Louisiana NE., suite 10000, Albuquerque, NM 87110. All claims should be addressed to the attention of Steven Hamp and sent by registered or certified mail, return receipt requested.

FOR FURTHER INFORMATION CONTACT: Steven Hamp, Uranium Mill Tailings Remedial Action Project Office, U.S. Department of Energy, (505) 845–4628.

SUPPLEMENTARY INFORMATION: The Department of Energy is issuing a final rule under 10 CFR Part 765 published elsewhere in this issue to implement the requirements of Title X of the Energy Policy Act of 1992 (sections 1001–1004 of Public Law 102–486, 42 U.S.C. 2296 *et seq.*) and to establish the procedures for eligible licensees to submit claims for reimbursement. Title X requires the Department of Energy to reimburse eligible uranium and thorium licensees for certain costs of decontamination, decommissioning, reclamation, and other remedial action incurred by licensees at active uranium and thorium processing sites to remediate byproduct material generated as an incident of sales to the United States Government. To be reimbursable, costs of remedial action must be for work which is necessary to comply with applicable requirements of the Uranium Mill Tailings Radiation Control Act of 1978 or, where appropriate, with requirements established by a state pursuant to a discontinuance agreement under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021). Claims for reimbursement of costs of remedial action must be supported by reasonable documentation as determined by the Department of Energy in accordance with 10 CFR part 765. Section 1001(b)(2) of the Act limits the amount of reimbursement to any one licensee of an active uranium mill tailings site to an amount not to exceed $5.50, as adjusted for inflation, multiplied by the number of dry short tons of byproduct material located at the site on October 24, 1992, and generated as an incident of sales to the United States. Total reimbursement, in the aggregate, for work performed at the active uranium sites shall not exceed $270 million, as adjusted for inflation. Total reimbursement for work performed at the active thorium processing site shall not exceed $40 million, as adjusted for inflation, and is limited to costs incurred for offsite disposal.

Funds for the reimbursements will be provided from the Uranium Enrichment Decontamination and Decommissioning Fund established at the United States Department of Treasury pursuant to section 1801 of the Atomic Energy Act of 1954 (42 U.S.C. 2297g). Payment or obligation of funds shall be subject to the requirements of the Anti-Deficiency Act (31 U.S.C. 1341).

Authority: Section 1001–1004 of Pub. L. No. 102–486, 106 Stat. 2776 (42 U.S.C. 2296a *et seq.*)

Issued in Washington, DC, on this 10th day of May, 1994.

Thomas P. Grumbly,

Assistant Secretary for Environmental Management.

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